US011857418B2

(12) **United States Patent**
Yellin et al.

(10) **Patent No.: US 11,857,418 B2**
(45) **Date of Patent: Jan. 2, 2024**

(54) **ANNULI ENGAGEMENT AND RESHAPING USING NATURAL FIDUCIALS**

(71) Applicant: **VALCARE, INC.**, Herzelyia Pituach (IL)

(72) Inventors: **Nadav Yellin**, Even Yehuda (IL); **David Meerkin**, Jerusalem (IL); **Yoav Rozen**, Binyamina (IL); **Shuki Porath**, Haifa (IL); **Aviad Galler**, Tel Aviv (IL); **Yuri Falkovich**, Pardes Hana (IL); **Guy Rogel**, Haifa (IL)

(73) Assignee: **VALCARE, INC.**, Herzelyia Pituach (IL)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **18/245,298**

(22) PCT Filed: **Sep. 15, 2021**

(86) PCT No.: **PCT/US2021/071468**
§ 371 (c)(1),
(2) Date: **Mar. 14, 2023**

(87) PCT Pub. No.: **WO2022/061345**
PCT Pub. Date: **Mar. 24, 2022**

(65) **Prior Publication Data**

US 2023/0285148 A1 Sep. 14, 2023

Related U.S. Application Data

(60) Provisional application No. 63/078,759, filed on Sep. 15, 2020.

(51) **Int. Cl.**
A61F 2/24 (2006.01)
A61F 2/00 (2006.01)

(52) **U.S. Cl.**
CPC ***A61F 2/2466*** (2013.01); ***A61F 2/2448*** (2013.01); *A61F 2002/0081* (2013.01); *A61F 2220/0016* (2013.01); *A61F 2230/0065* (2013.01)

(58) **Field of Classification Search**
CPC A61F 2/2442; A61F 2/2445; A61F 2/2448; A61F 2/2466
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

2012/0123531 A1 5/2012 Tsukashima et al.
2019/0053905 A1 2/2019 Alon
2020/0163763 A1 5/2020 Zipory et al.

FOREIGN PATENT DOCUMENTS

WO 2018035118 A1 2/2018

OTHER PUBLICATIONS

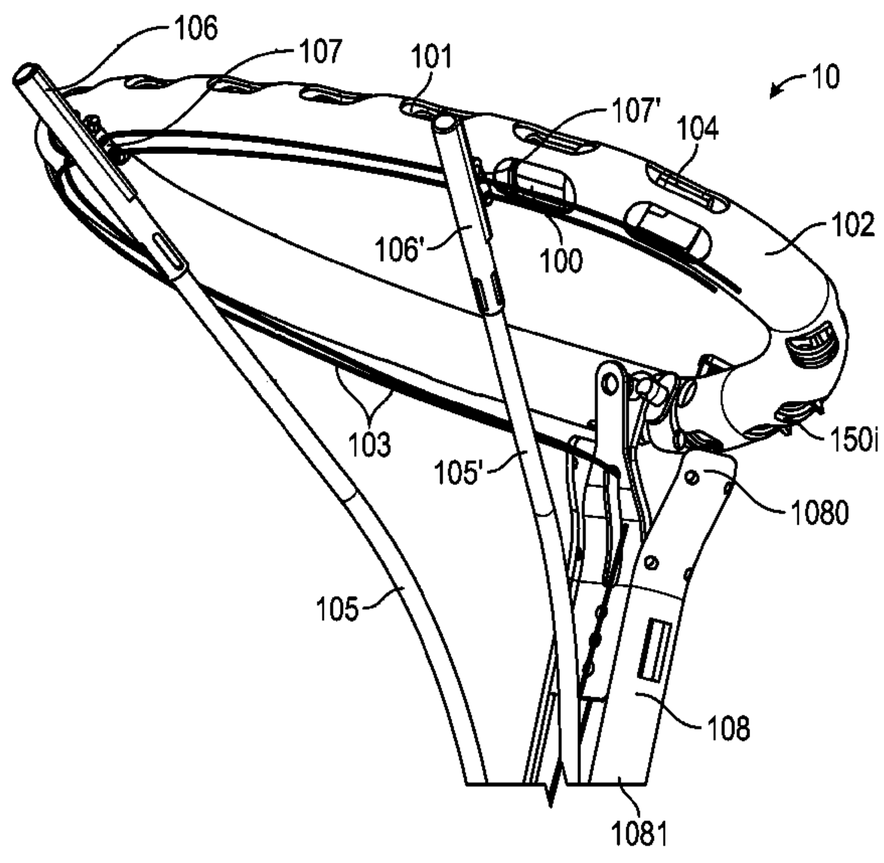
PCT/US2021/071468 , International Search Report and Written Opinion, dated Jan. 19, 2022, 19 pages.

Primary Examiner — William H Matthews
(74) *Attorney, Agent, or Firm* — Dorsey & Whitney LLP

(57) **ABSTRACT**

The present disclosure relates to methods and systems for aligning annuloplasty rings during surgical procedures and selectively engaging portions of the targeted annuli. Specifically, the disclosure is directed to methods and systems for aligning an annuloplasty ring or a toroidal portion thereof with natural fiducials present at or near an annular target, and engaging the annulus at the points aligned with the natural fiducials.

38 Claims, 12 Drawing Sheets



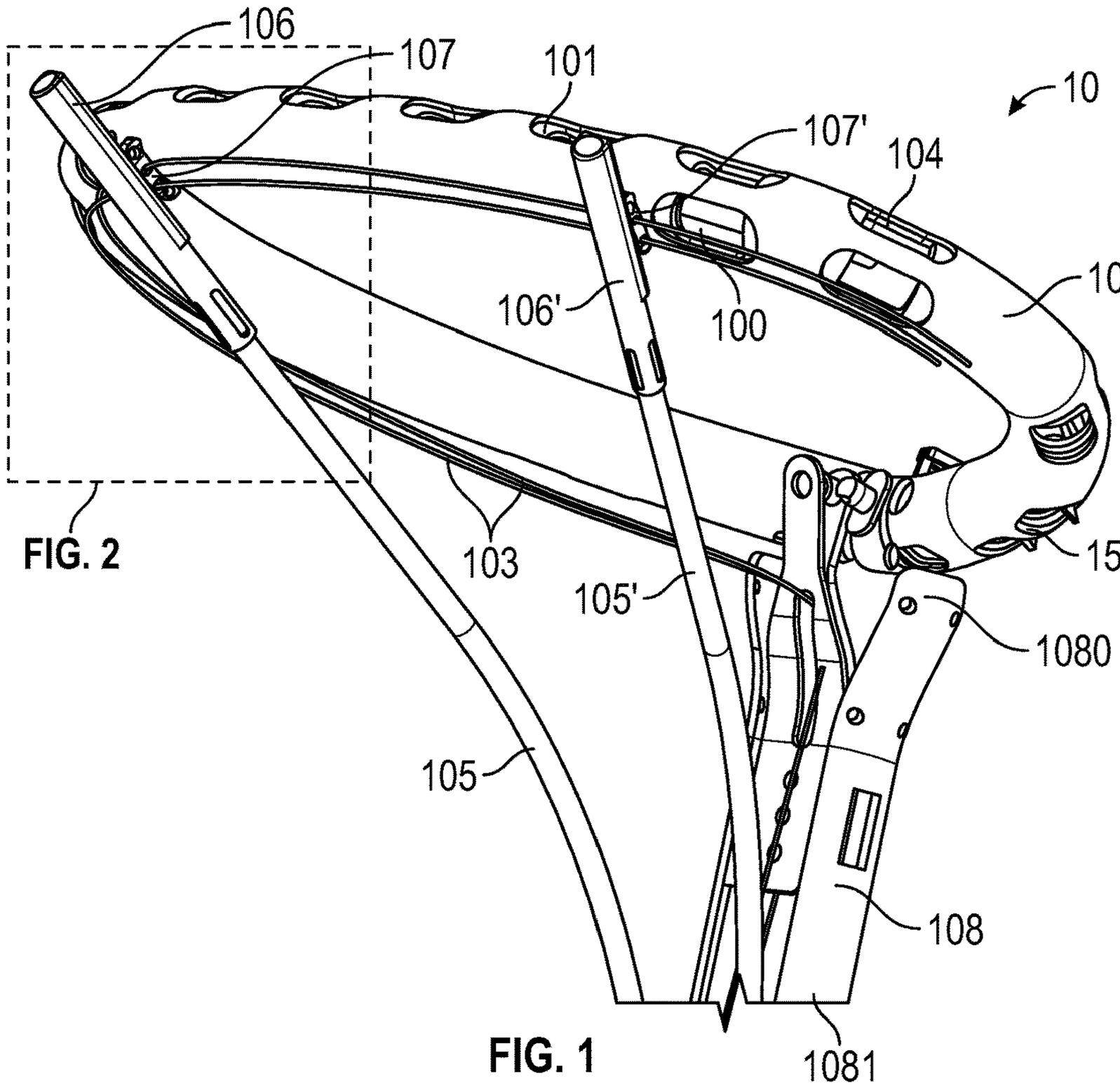


FIG. 1

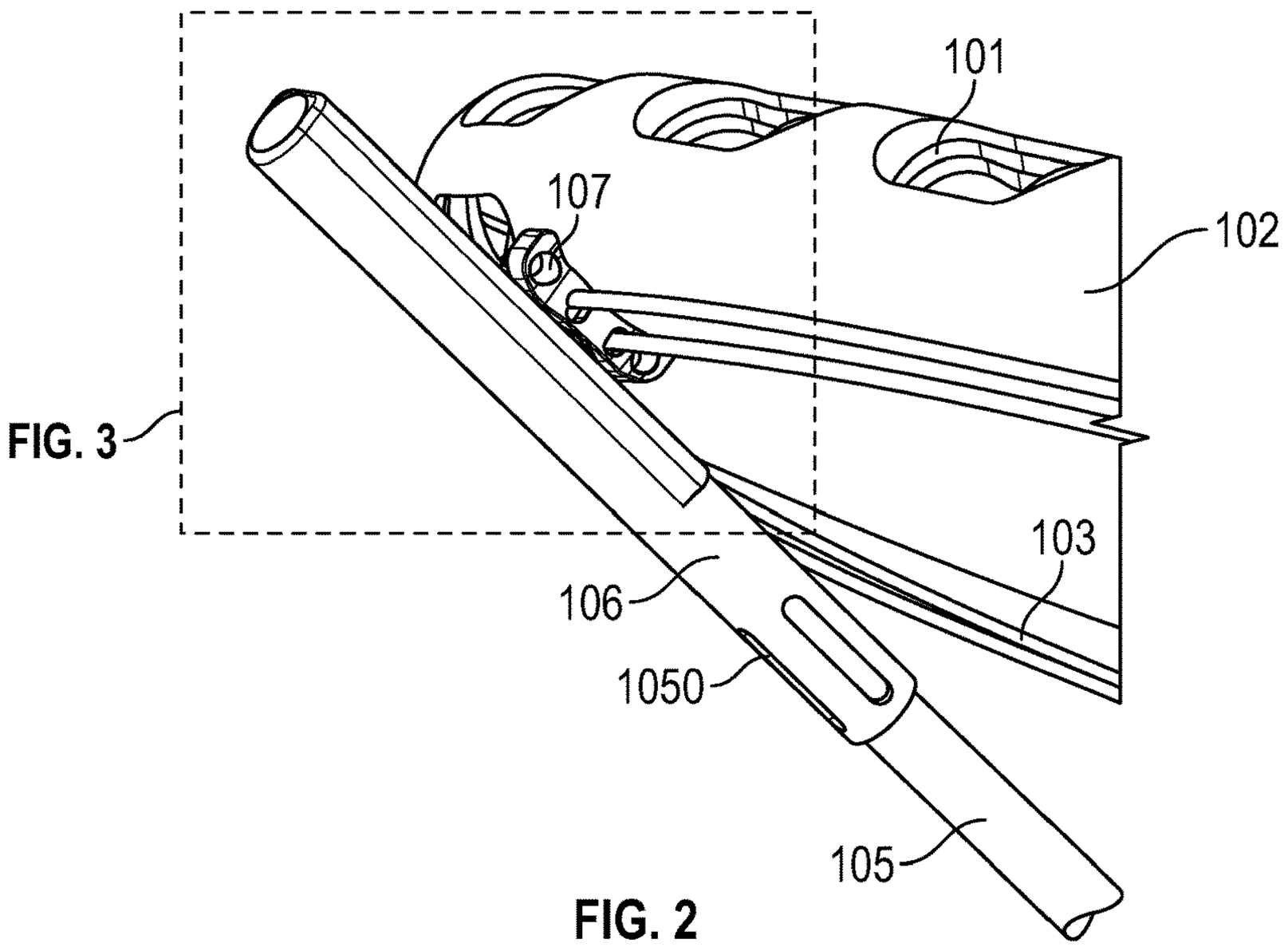


FIG. 2

FIG. 3

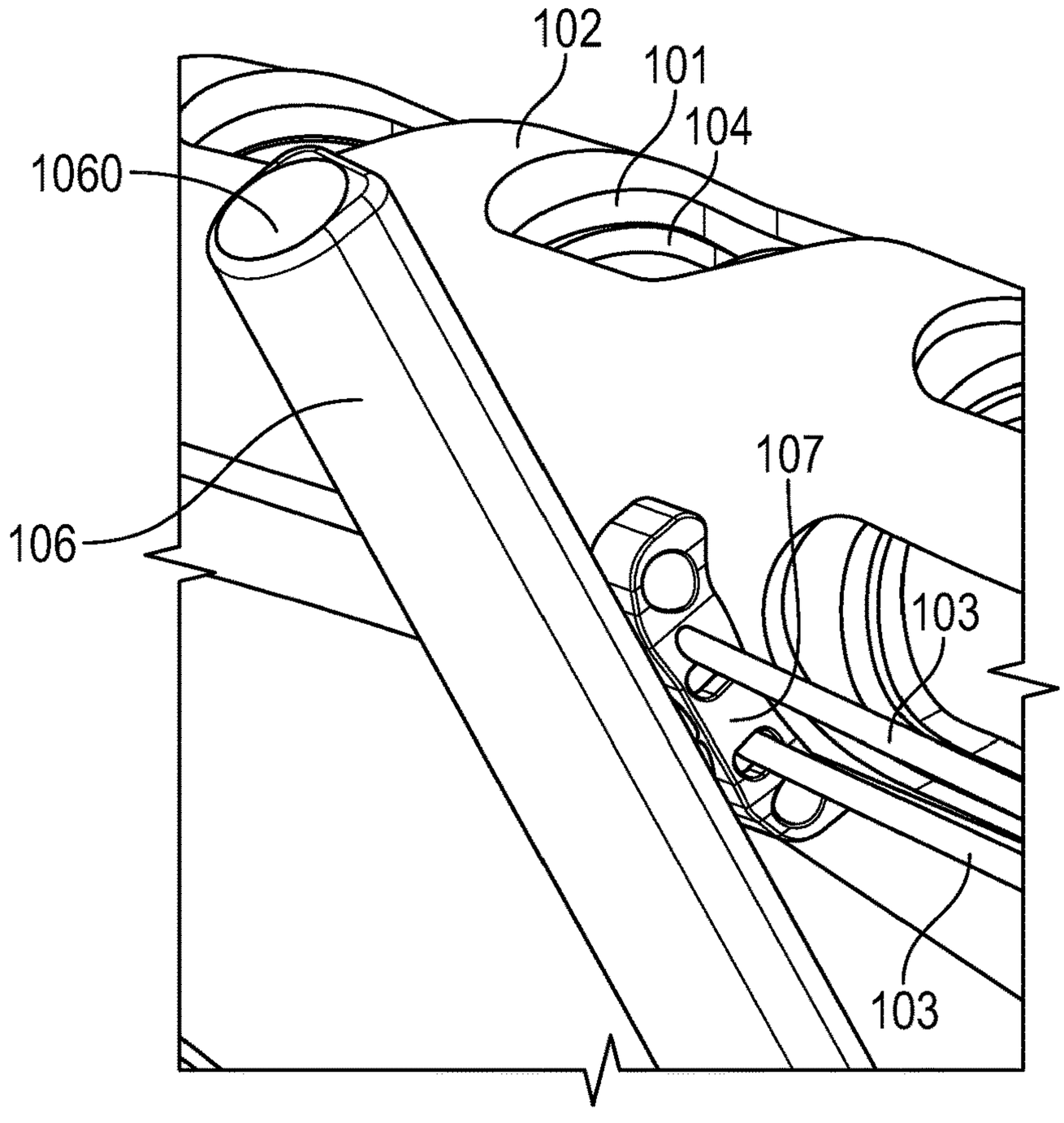

102
101
104
1060
107
106
103
103

FIG. 3

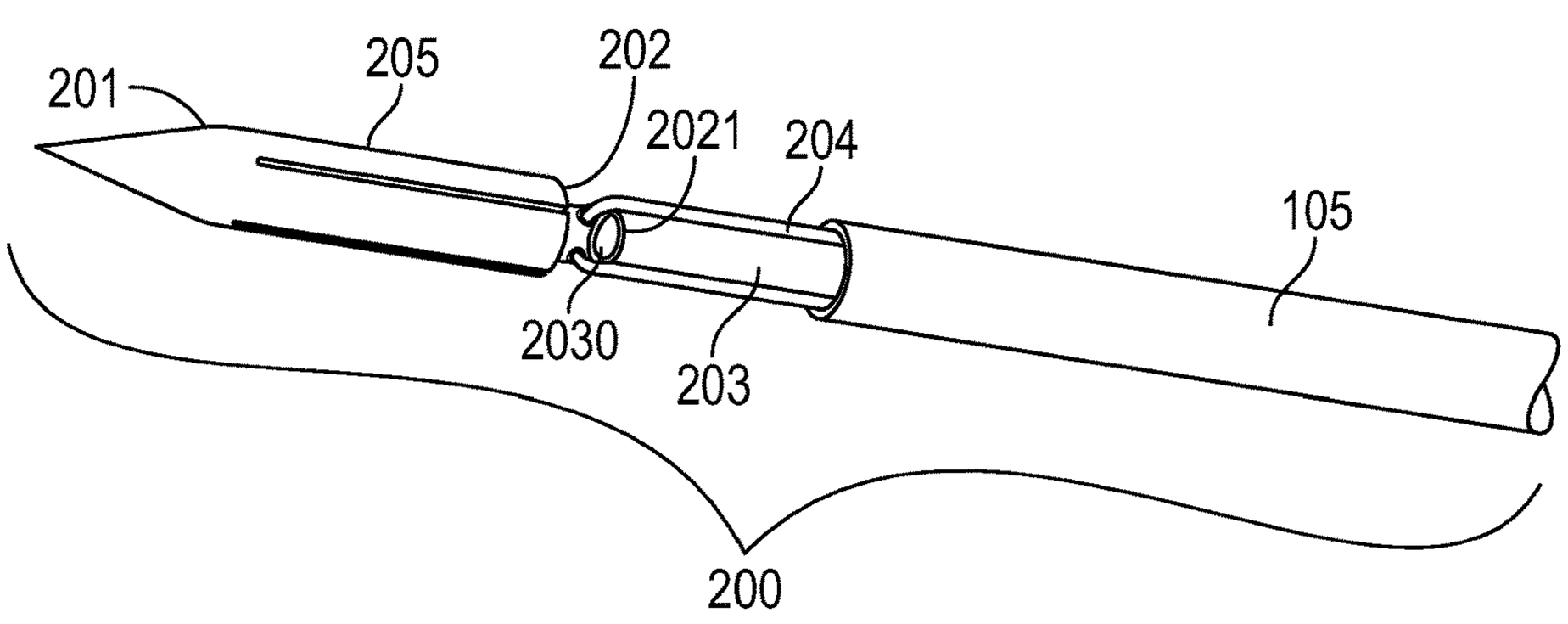

205
202
201
2021
204
105
2030
203
200

FIG. 4

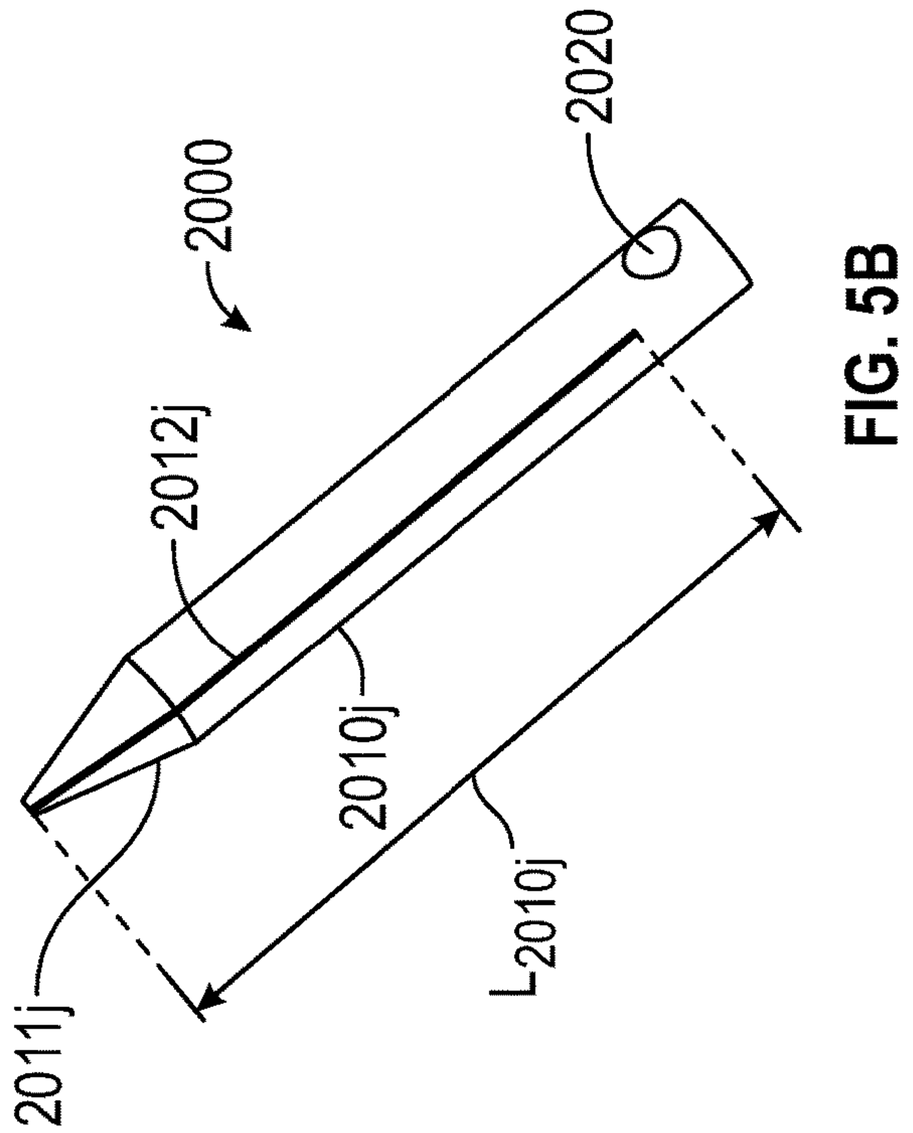


FIG. 5B

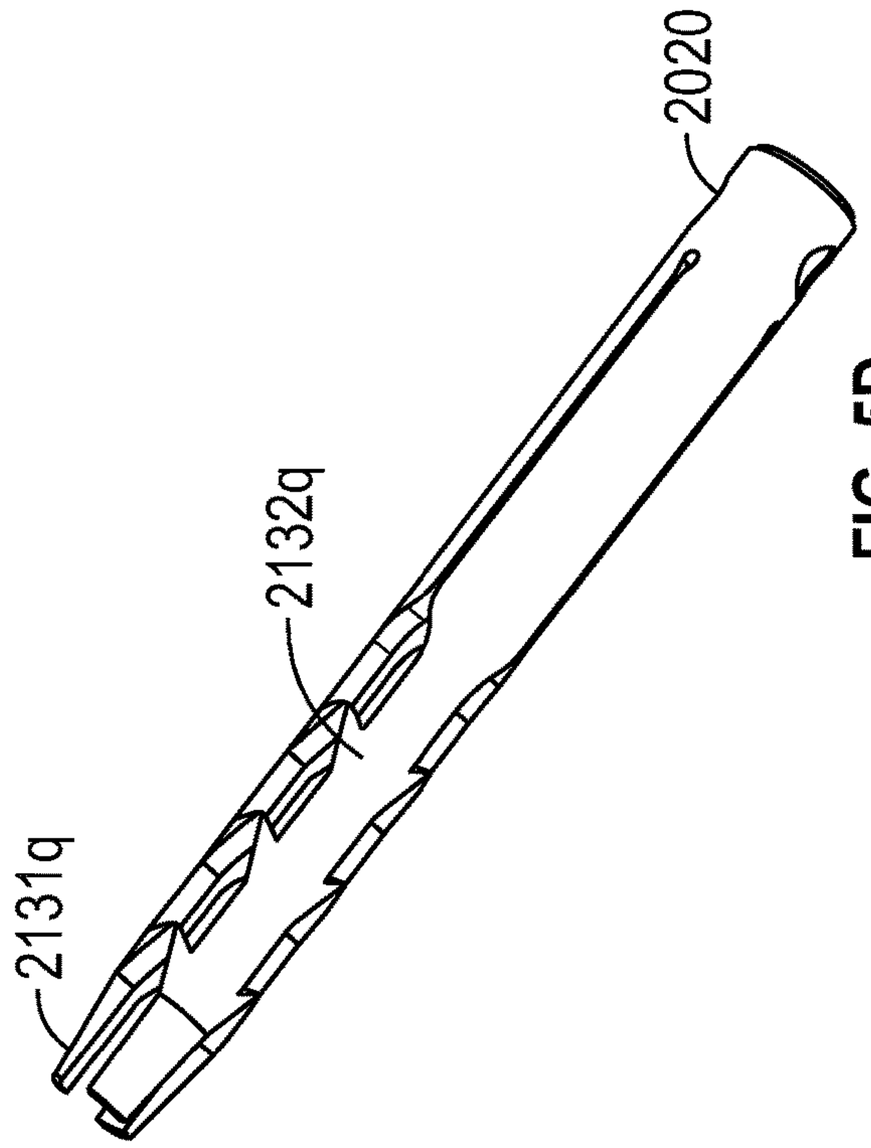


FIG. 5D

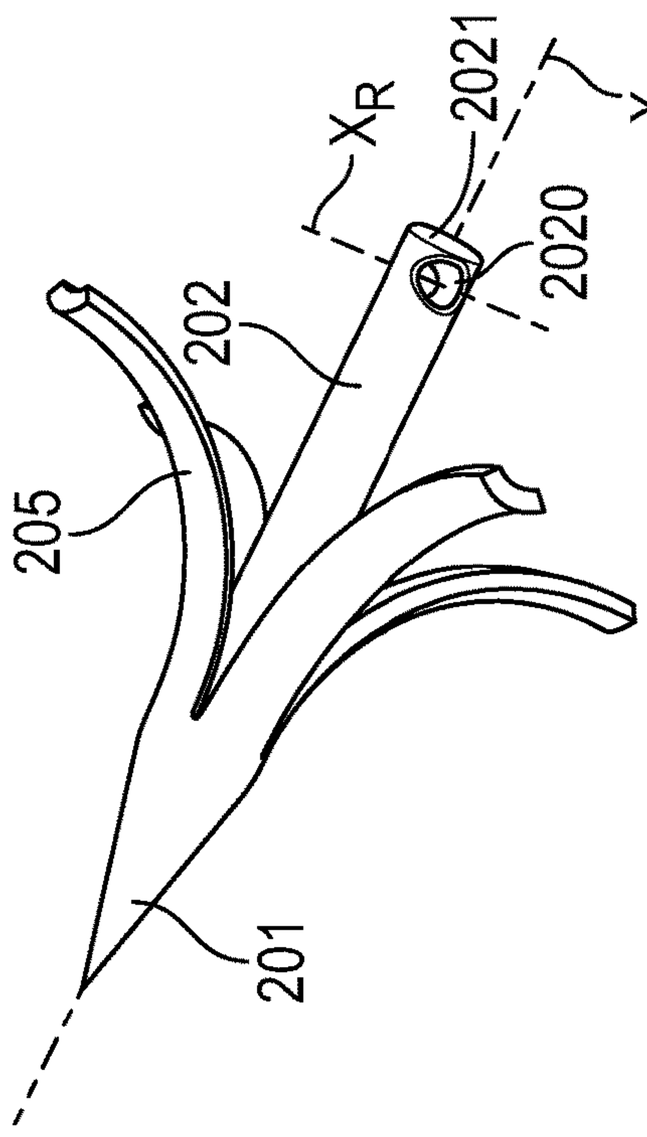


FIG. 5A

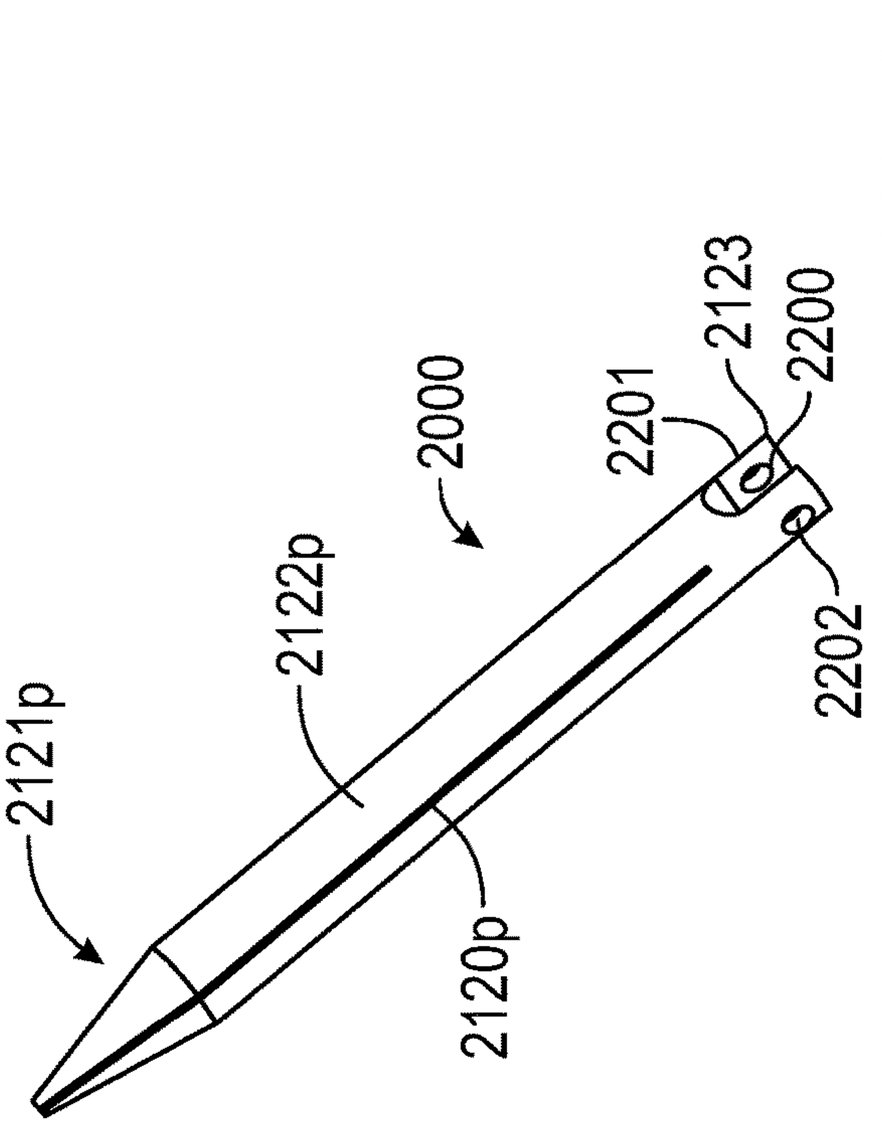


FIG. 5C

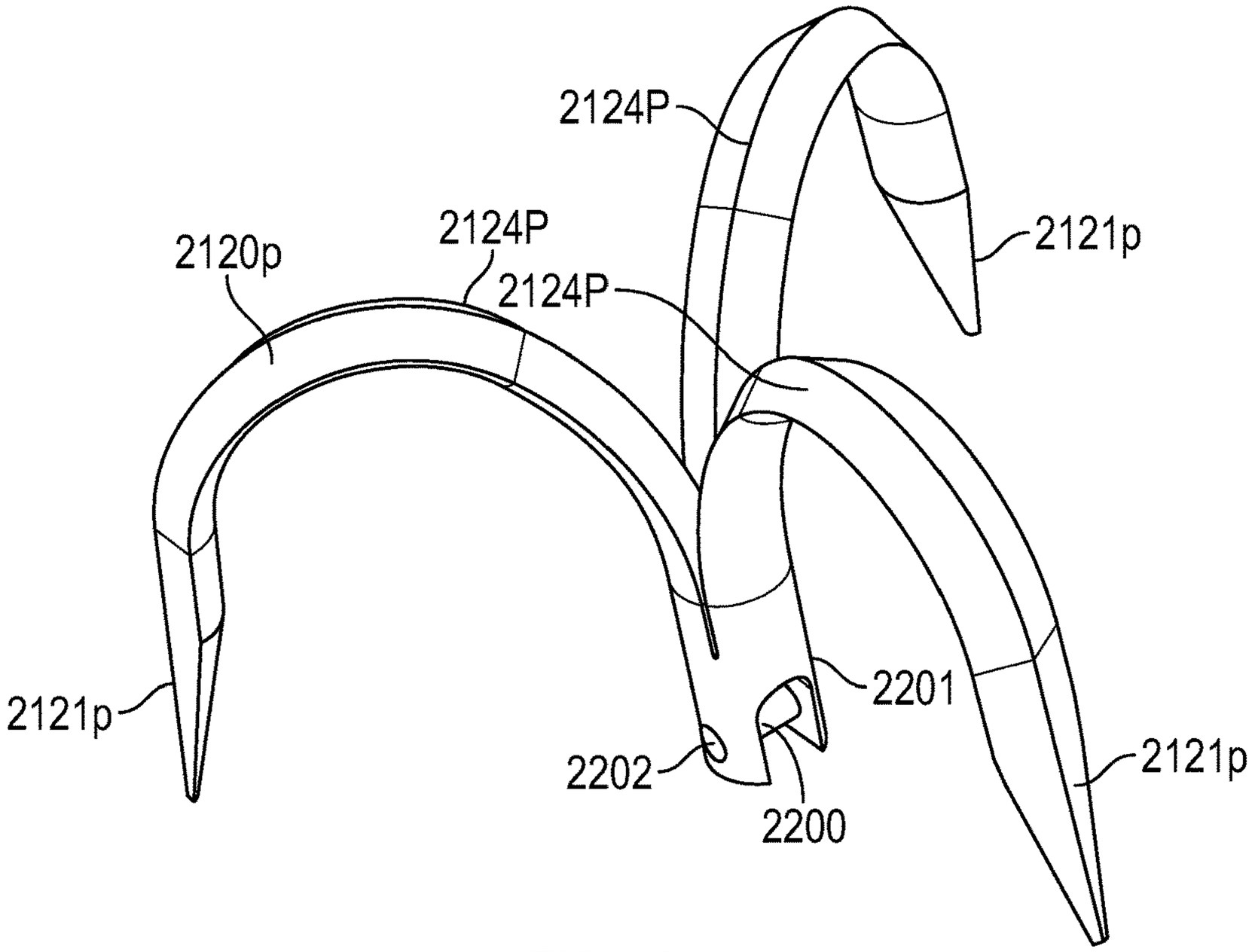

2124P
2120p
2124P
2124P
2121p
2121p
2201
2202
2200
2121p

FIG. 6A

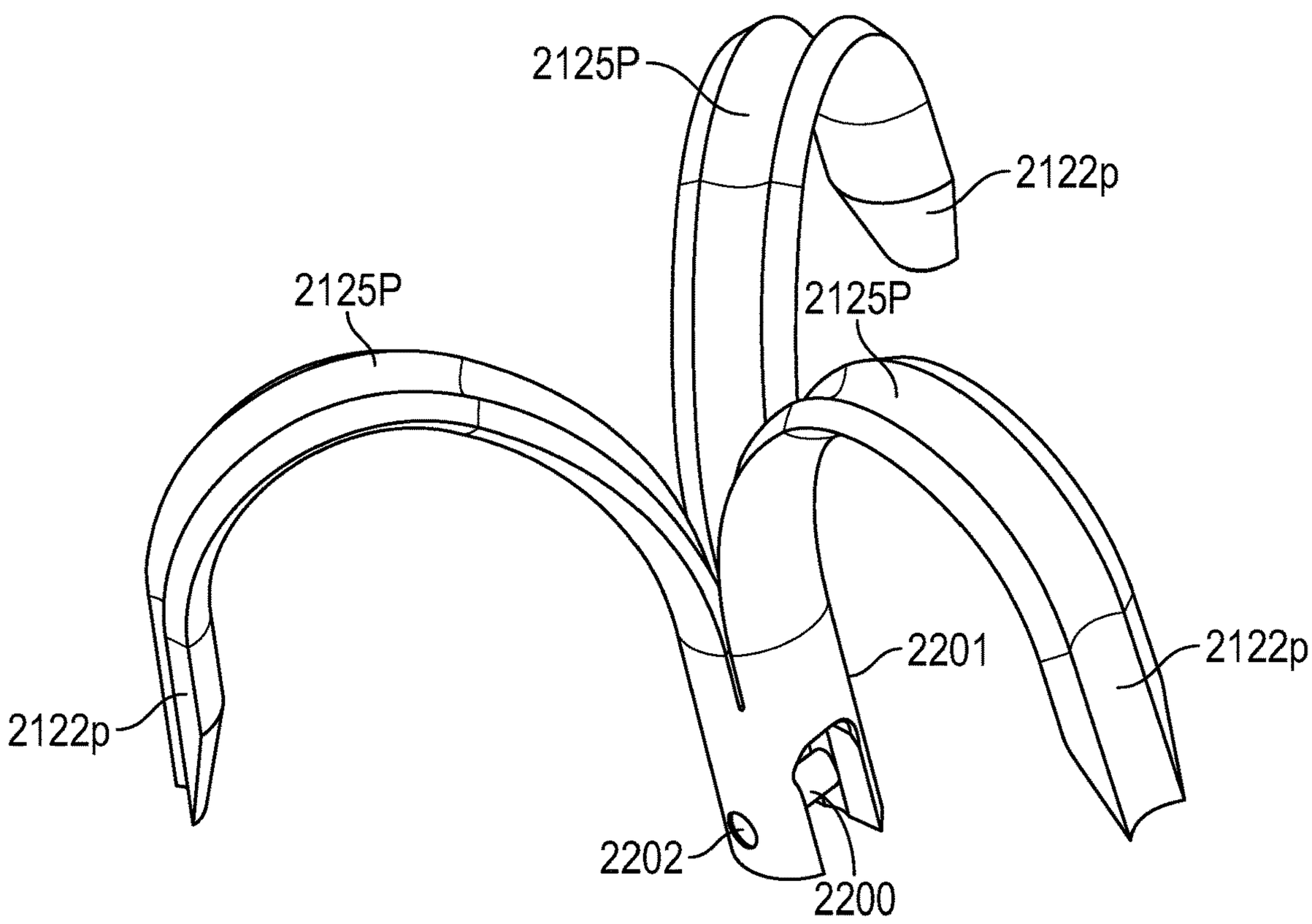

2125P
2122p
2125P
2125P
2201
2122p
2122p
2202
2200

FIG. 6B

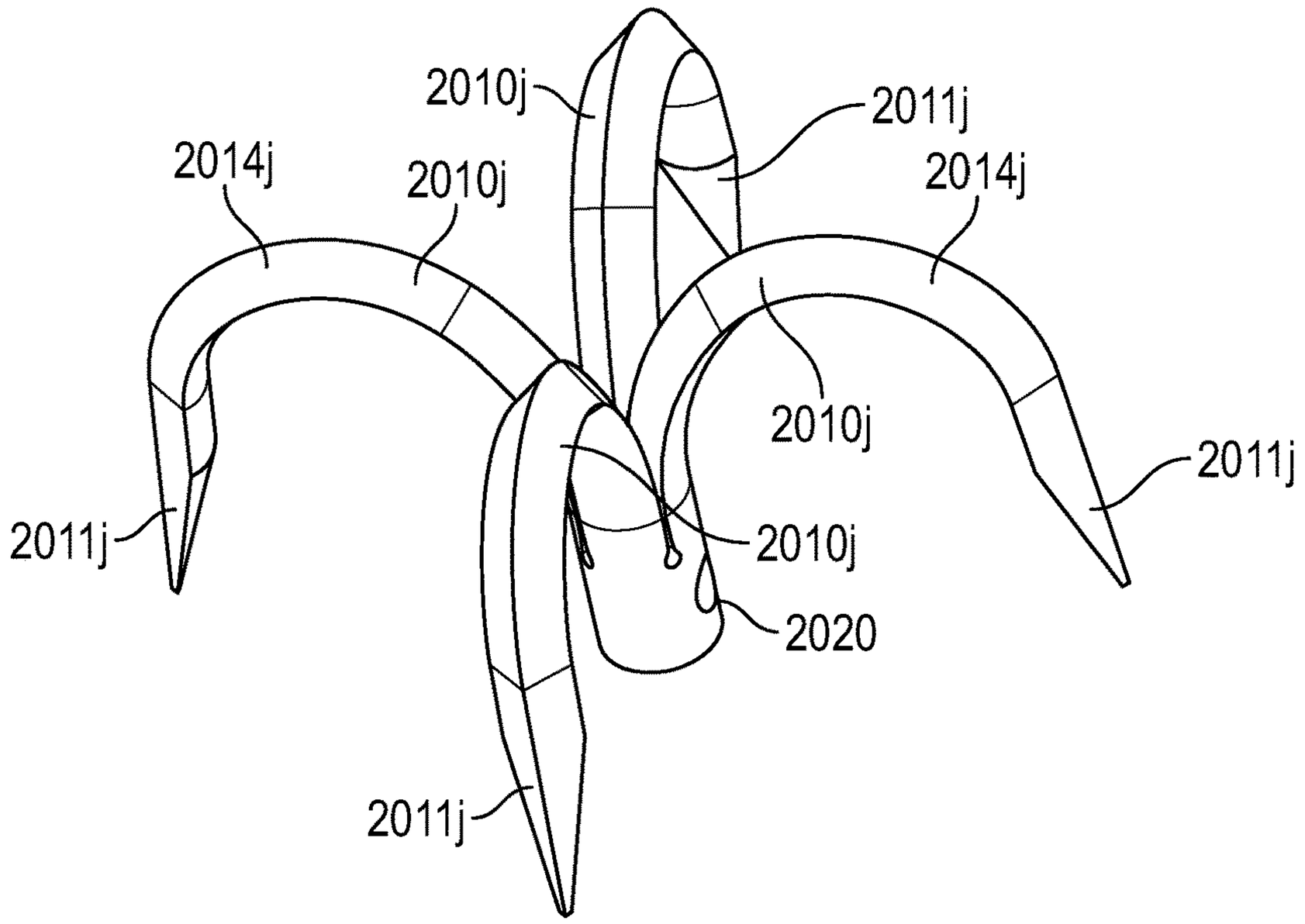

2010j
2011j
2014j
2010j
2014j
2010j
2011j
2011j
2010j
2020
2011j

FIG. 7A

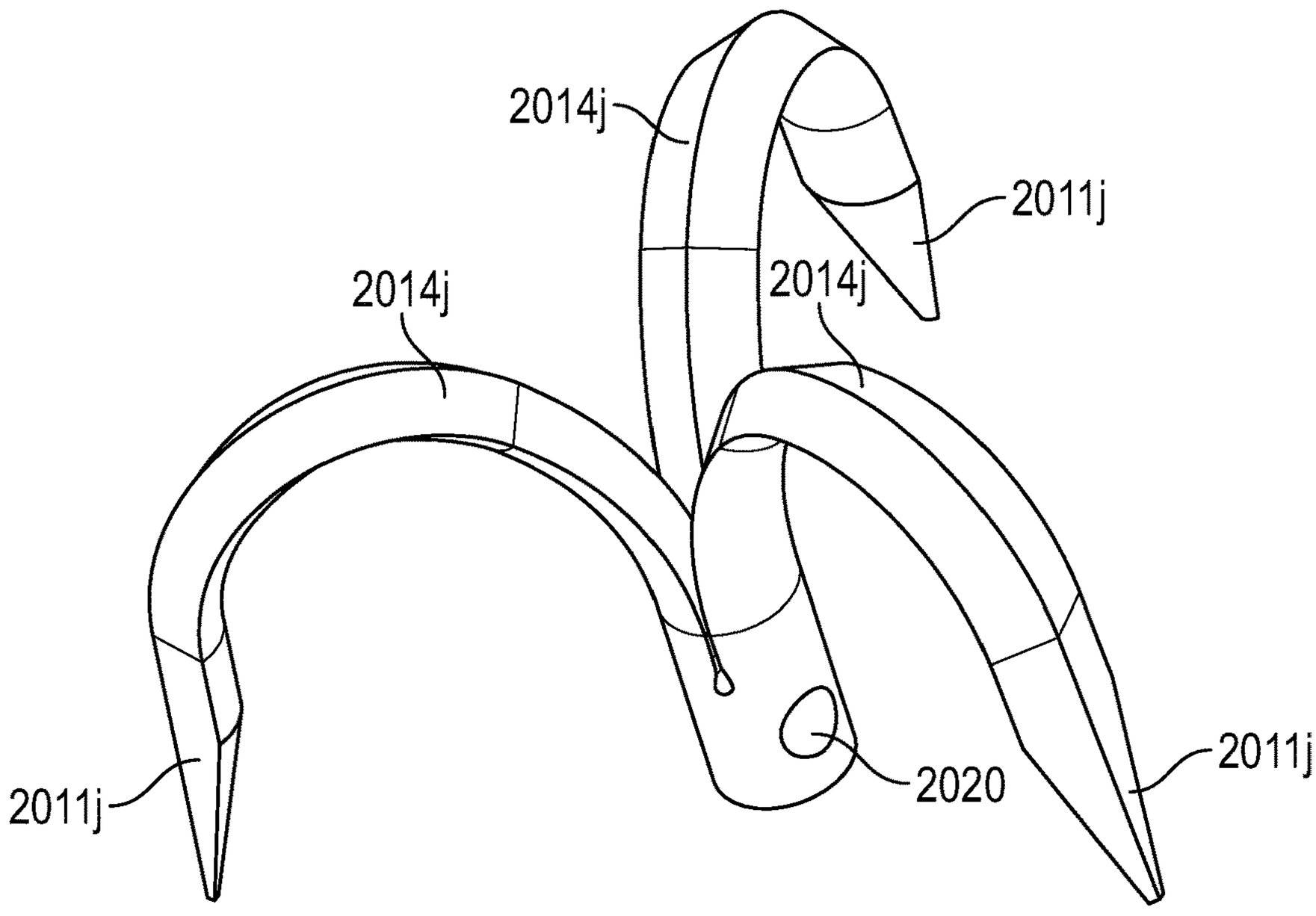

2014j
2011j
2014j
2014j
2011j
2020
2011j

FIG. 7B

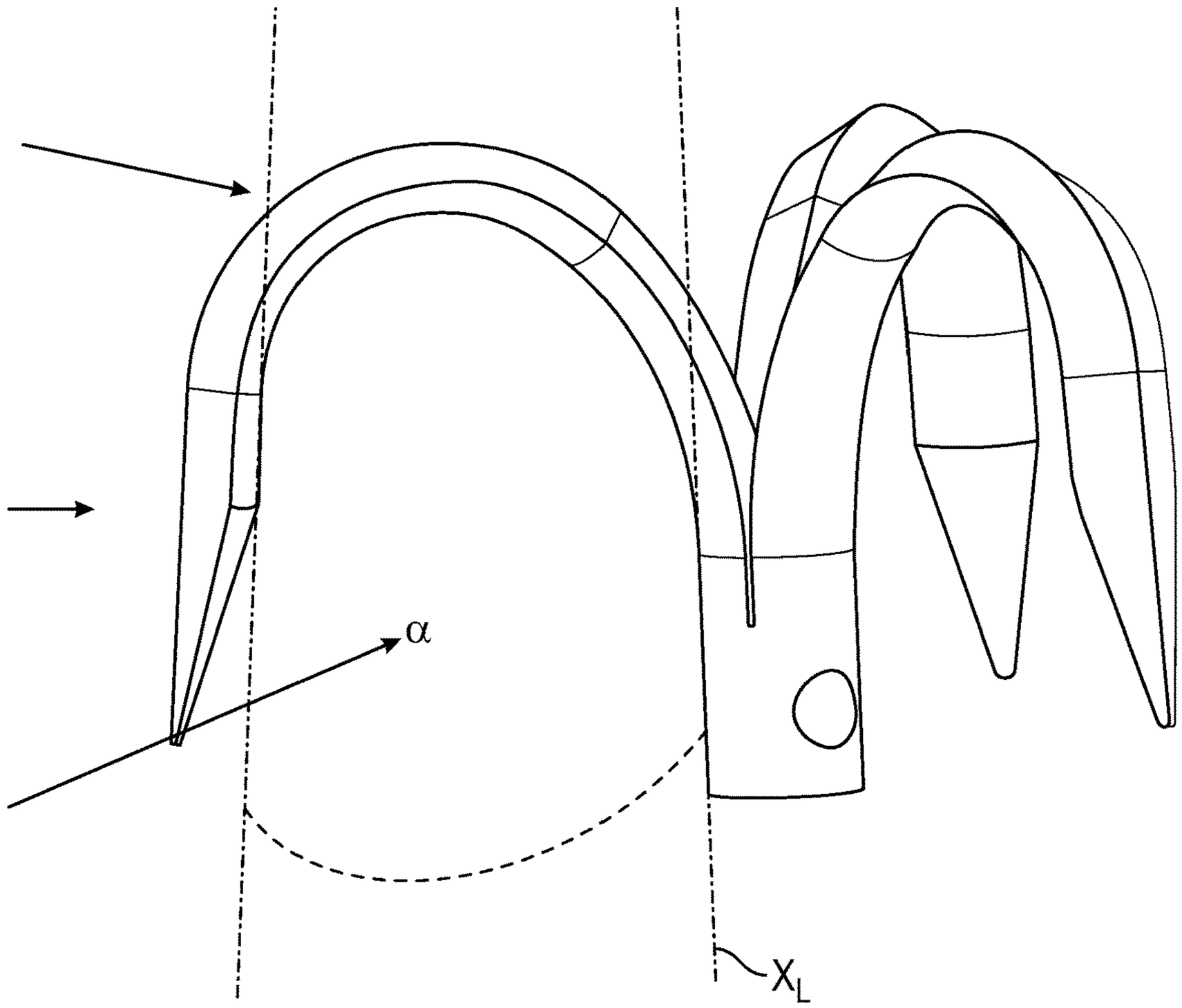


FIG. 8

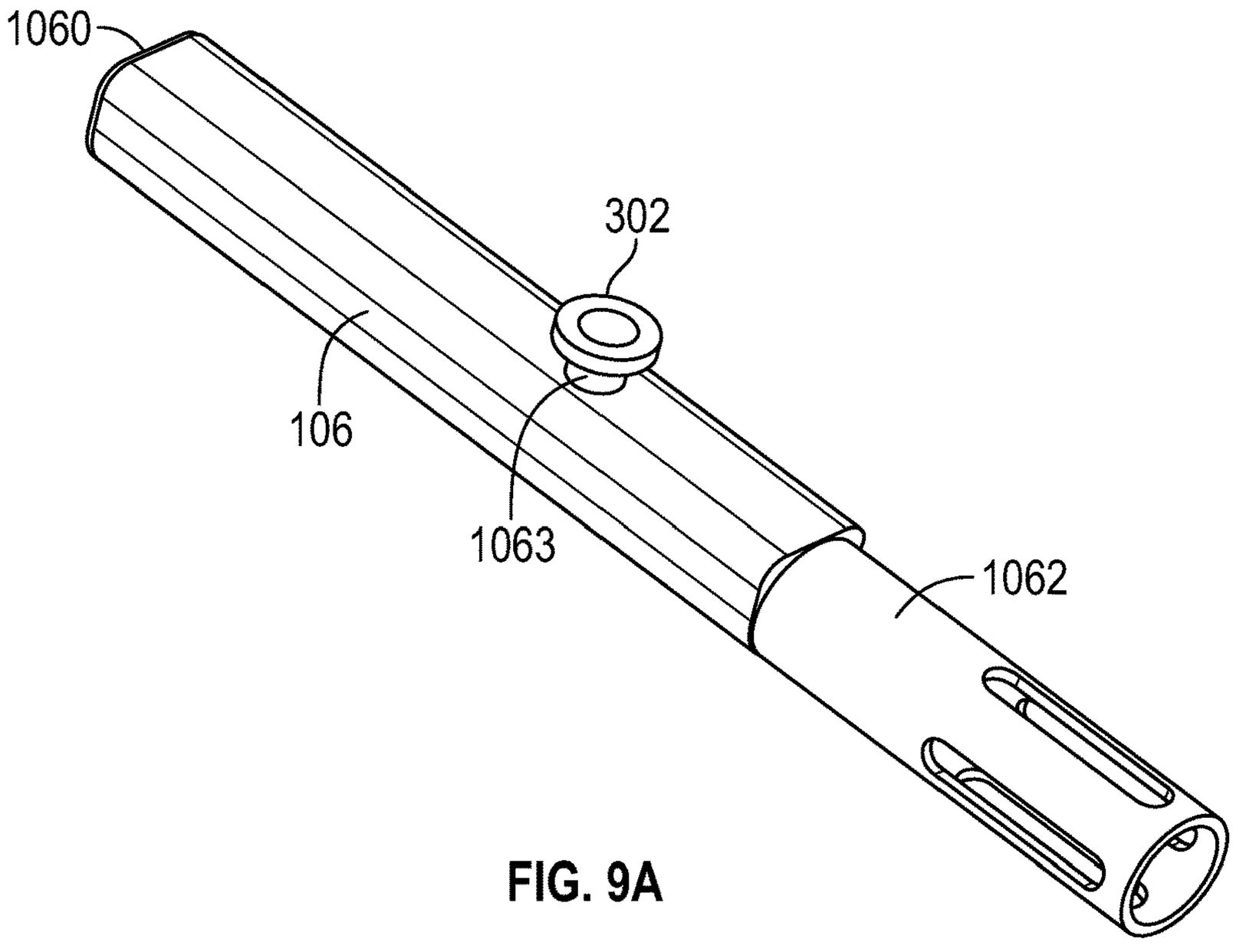


FIG. 9A

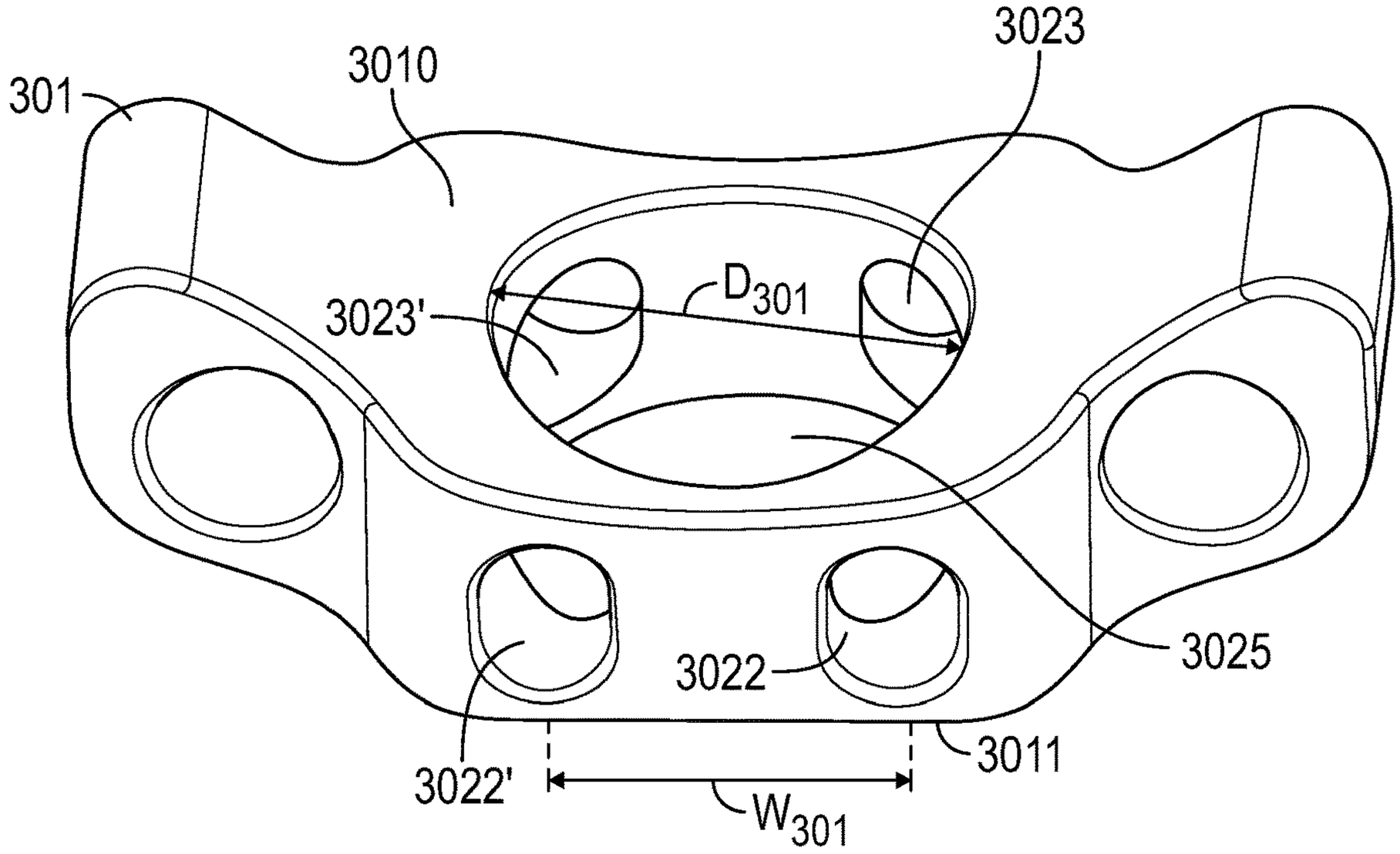

301
3010
3023
3023'
D_{301}
3022
3025
3022'
3011
W_{301}

FIG. 9B

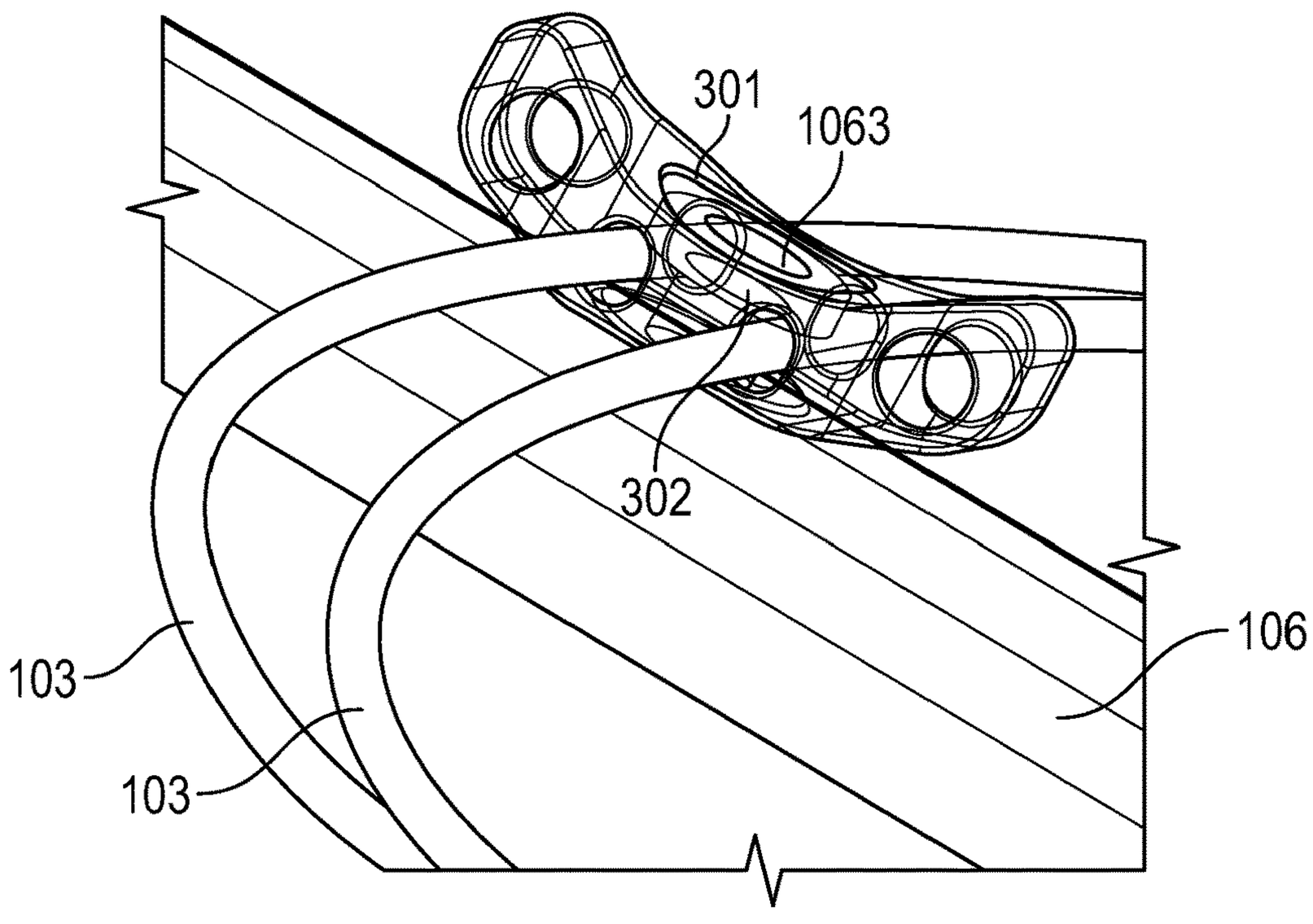

301
1063
302
103
103
106

FIG. 9C

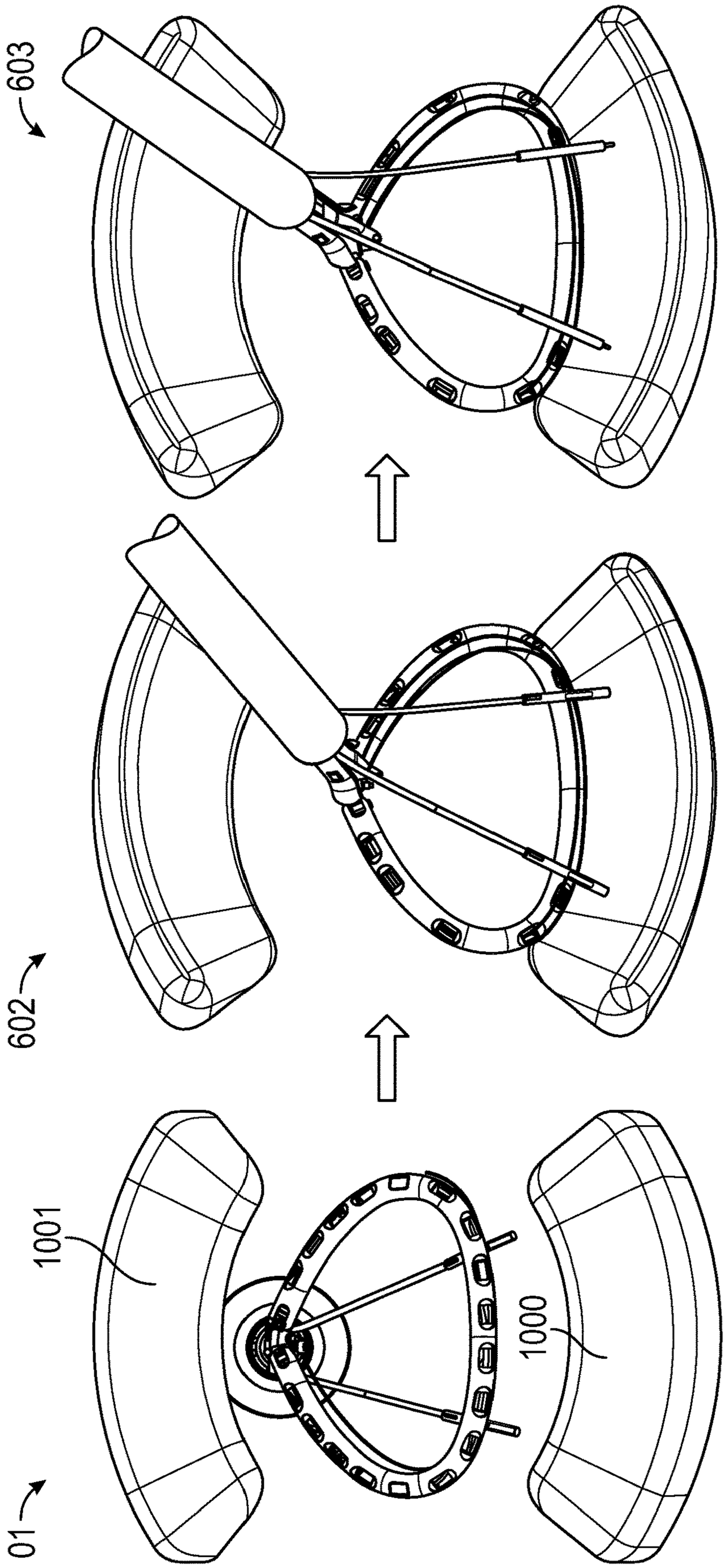


FIG. 10C

FIG. 10B

FIG. 10A

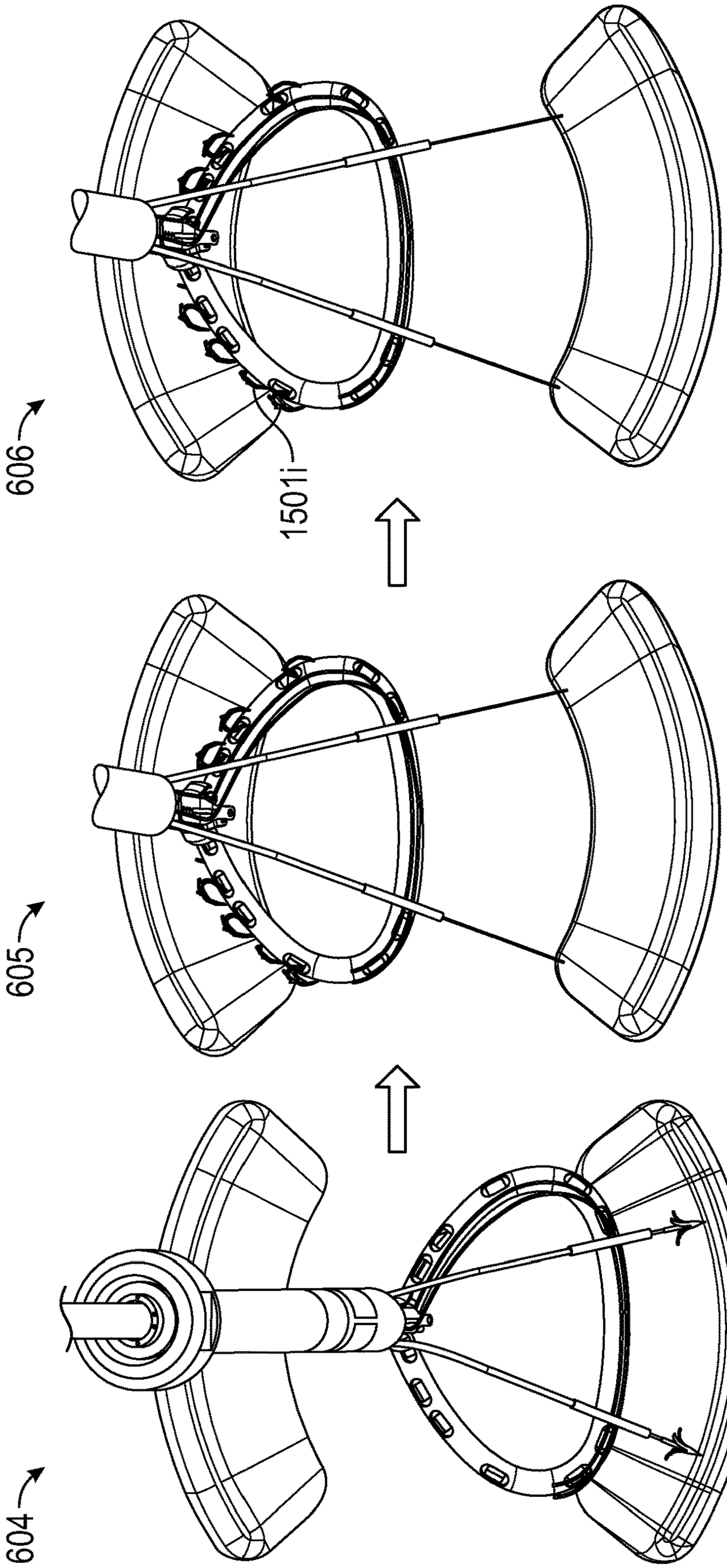


FIG. 10F

FIG. 10E

FIG. 10D

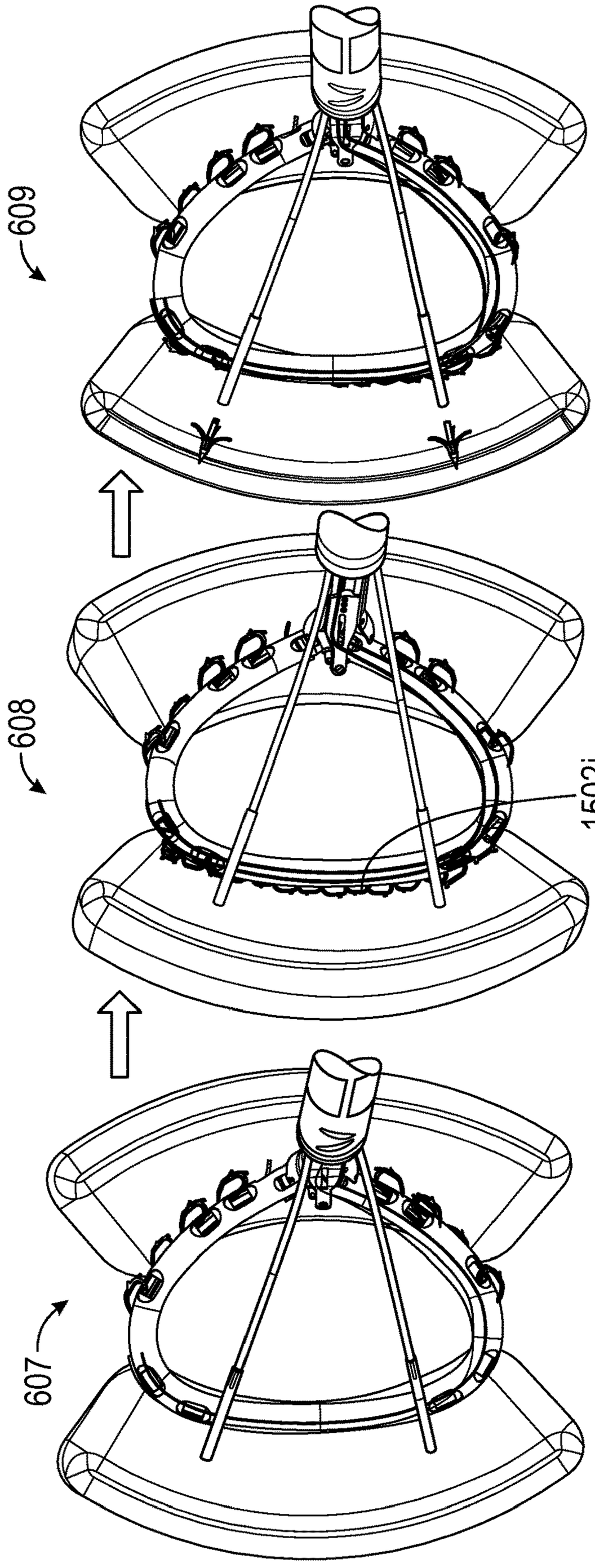


FIG. 10I

FIG. 10H

FIG. 10G

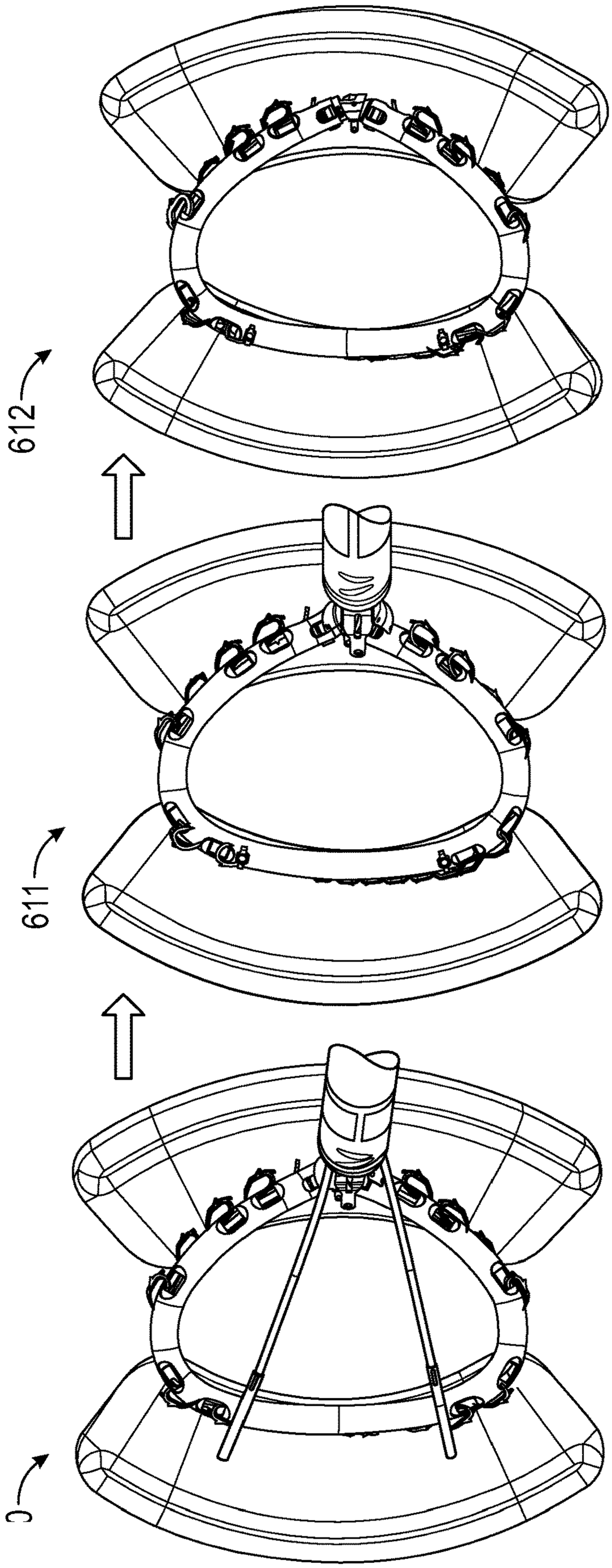


FIG. 10L

FIG. 10K

FIG. 10J

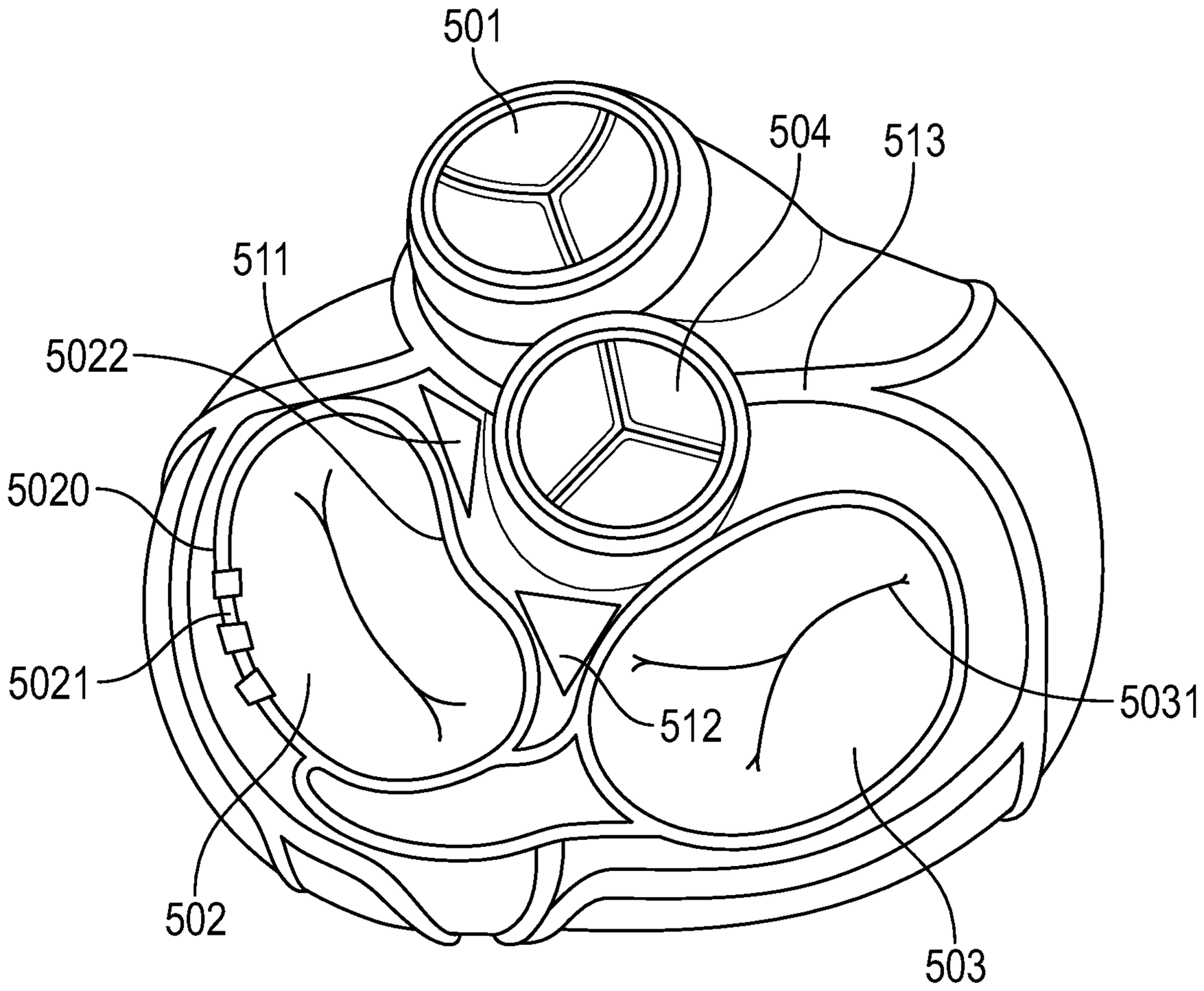


FIG. 11

ANNULI ENGAGEMENT AND RESHAPING USING NATURAL FIDUCIALS

RELATED CASES

This application is a 35 U.S.C. 371 National Phase application claiming priority to PCT/US2021/071468, filed Sep. 15, 2021, which claims priority to U.S. Provisional Application No. 63/078,759, filed on Sep. 15, 2020, and titled "ANNULI ENGAGEMENT AND RESHAPING USING NATURAL FIDUCIALS," both of which are hereby incorporated by reference in their entirety.

BACKGROUND

The present disclosure is directed to methods and systems for aligning annuloplasty rings during surgical procedures and selectively engaging portions of the targeted annuli. Specifically, the disclosure is directed to methods and systems for aligning an annuloplasty ring or a toroidal portion thereof with natural fiducials present at or near an annular target, and engaging the annulus at the points aligned with the natural fiducials.

Annuloplasty remains a fundamental component in heart valve repair. The annuloplasty ring may be used to restore the size and shape of the native annulus; to prevent future annular dilatation; and to provide functional annular support.

For example, dilation of the annulus of the mitral valve (MV) prevents the valve leaflets from fully coapting when the valve is closed, leading to mitral regurgitation (MR) of blood from the left ventricle into the left atrium.

Under typical circumstances, in MV repair using ring annuloplasty, in which a docking member is anchored to the annulus, drastically reduces the mobility of the central posterior leaflet, causing valve closure to be a single anterior leaflet process with a frozen posterior buttress. Accordingly, and to ensure full cooptation of the leaflets, it is advantageous to properly locate the annuloplasty ring within the annulus.

Similarly, tricuspid regurgitation (TR) of the tricuspid valve (TV), is thought to affect a majority of the population in the U.S. Regardless, relatively few tricuspid valve operations are performed annually due to various challenges associated with surgical or percutaneous transcatheter based treatment of TR.

The proposed technology aims to address the shortcomings of the current systems.

SUMMARY

In an exemplary implementation, provided herein is a device operable to align to at least one natural fiducial of an annular target and engage a portion of the annular target at the location aligned with the at least one natural fiducial, the device comprising: an annuloplasty ring, or a first toroidal portion thereof, each having an outer hollow tube with a plurality of slotted backbone therein, the annuloplasty ring or its toroidal portion are each operable to change from an insertion configuration to an operable configuration; an alignment and engagement construction comprising at least one cannula, the cannula having a sleeve coupled to a distal end of the cannula, the sleeve being releasably coupled to the outer hollow tube via a coupling sub-assembly, the construction operable to align with and engage the at least one natural fiducial; and a delivery catheter having a proximal end and a distal end, adapted, sized and configured to accommodate: the alignment and engagement construction, the coupling assembly and the annuloplasty ring or the first toroidal portion thereof in its insertion configuration, and wherein the delivery catheter is operable, once the annuloplasty ring or its first toroidal portion is inserted, to alter the annuloplasty ring, or its first toroidal portion from the insertion configuration to the operable configuration.

In another exemplary implementation, provided herein is a method for aligning an annuloplasty ring or its first toroidal portion to at least one natural fiducial of an annular target and engage a portion of the annular target aligned with the at least one natural fiducial, implementable in a system comprising an annuloplasty ring, or a first toroidal portion thereof, each having an outer hollow tube with a plurality of slotted backbone therein, the annuloplasty ring or its toroidal portion are each operable to change from an insertion configuration to an operable configuration; an alignment and engagement construction comprising at least one cannula, the cannula having a sleeve coupled to a distal end of the cannula, the sleeve being releasably coupled to the outer hollow tube via a coupling sub-assembly, the construction operable to align with and engage the at least one natural fiducial; and a delivery catheter having a proximal end and a distal end, adapted, sized and configured to accommodate: the alignment and engagement construction, the coupling assembly and the annuloplasty ring or the first toroidal portion thereof in its insertion configuration, and wherein the delivery catheter is operable, once the annuloplasty ring or its first toroidal portion is inserted, to alter the annuloplasty ring, or its first toroidal portion from the insertion configuration to the operable configuration, the method comprising: using the delivery catheter, introducing the annuloplasty ring or the first toroidal portion thereof to the annular target site; using the delivery catheter, altering the insertion configuration of the annuloplasty ring or the first toroidal portion thereof to the operable configuration; using the alignment and engagement construction, aligning the at least one sleeve with the at least one natural fiducial; engaging the annular target at the location aligned with the at least one natural fiducial; and releasing the sleeve from the outer hollow tube.

In yet another embodiment, the cannula comprises a harpoon operable to engage the natural fiducial, wherein the harpoon comprises: a self-penetrating tip; a foreshaft distally coupled to the self-penetrating tip, the foreshaft defining a radial aperture disposed along the foreshaft's longitudinal axis; a pushrod, having a proximal end defining an axial socket sized and releasably coupled to the distal end of the foreshaft; optionally, a tether looped through the radial aperture; and optionally, at least one spur, operably coupled to the self-penetrating head, configured to transition from a first insertion position to a second anchoring position.

In still yet another exemplary implementation, the annuloplasty ring or its first toroidal portion each has at least one anterior and one posterior zone, each zone comprising a plurality of internal anchor members located at least partially within the corresponding outer hollow tube, each anchor operable to selectably extend radially from the outer hollow tube and engage an anterior and a posterior portion of the annular target, wherein the method further comprises: retracting the delivery catheter to abut the posterior portion of the annulus; using the plurality of anchoring members in the posterior portion of the annuloplasty ring or its first toroidal portion, anchoring the annuloplasty ring or its first toroidal portion to the posterior portion of the annular target; using the tether, pulling the anchored posterior portion of the annulus toward the engaged (anterior) portion of the annu-

lus; and using the plurality of anchoring members in the anterior portion of the annuloplasty ring or its first toroidal portion, anchoring the annuloplasty ring or its first toroidal portion to the anterior portion of the annular target.

In an exemplary implementation, provided herein is the use of a system operable to align an annuloplasty ring or its first toroidal portion to at least one natural fiducial of an annular target and engage a portion of the annular target aligned with the at least one natural fiducial, the system comprising: an annuloplasty ring or a first toroidal portion thereof, each having an outer hollow tube with a plurality of slotted backbone therein, the annuloplasty ring or its toroidal portion are each operable to change from an insertion configuration to an operable configuration; an alignment and engagement construction comprising at least one cannula, the cannula having a sleeve coupled to a distal end of the cannula, the sleeve being releasably coupled to the outer hollow tube via a coupling sub-assembly, the construction operable to align with and engage the at least one natural fiducial; and a delivery catheter having a proximal end and a distal end, adapted, sized and configured to accommodate: the alignment and engagement construction, the coupling assembly and the annuloplasty ring or the first toroidal portion thereof in its insertion configuration, and wherein the delivery catheter is operable, once the annuloplasty ring or its first toroidal portion is inserted, to alter the annuloplasty ring or its first toroidal portion from the insertion configuration to the operable configuration, in the process for aligning an annuloplasty ring, or its first toroidal portion to at least one natural fiducial of an annular target and engage a portion of the annular target aligned with the at least one natural fiducial, by performing the steps of: using the delivery catheter; introducing the annuloplasty ring or the first toroidal portion thereof to the annular target site; using the delivery catheter; altering the insertion configuration of the annuloplasty ring or the first toroidal portion thereof to the operable configuration; using the alignment and engagement construction, aligning the at least one sleeve with the at least one natural fiducial; engaging the annular target aligned with the at least one fiducial; and releasing the sleeve from the outer hollow tube.

BRIEF DESCRIPTION OF THE DRAWINGS

The method implementable using the alignment and engagement systems disclosed herein will become apparent from the following detailed description when read in conjunction with the figures, which are exemplary, not limiting, and in which:

FIG. **1** illustrates an exemplary implementation of the alignment and engagement device;

FIG. **2** illustrates an enlarged portion from FIG. **1** showing the releasable attachment;

FIG. **3** illustrates the enlarged portion from FIG. **2** showing the releasable attachment in greater detail;

FIG. **4** illustrates an exemplary implementation of a harpoon used to engage a portion of the target annulus aligned with the natural fiducials;

FIGS. **5**A-**5**D illustrate a number of exemplary implementations of harpoon heads;

FIGS. **6**A, **6**B illustrate exemplary implementations of the multi-lance harpoon head illustrated in FIG. **5**C following actuation;

FIGS. **7**A, **7**B illustrate exemplary implementations of the multi-lance harpoon head illustrated in FIG. **5**B following actuation;

FIG. **8** illustrates an exemplary configuration of the multi-lance harpoon head of FIG. **7**B;

FIGS. **9**A-**9**C illustrate the components of the alignment and engagement constructions, with FIG. **9**A illustrating the sleeve, FIG. **9**B illustrating the docking member and FIG. **9**C illustrating the coupling of the sleeve to the docking member in the presence of the release cords;

FIGS. **10**A-**10**L are schematic illustrations of an exemplary implementation of the use of the devices disclosed, in the process of reshaping an annular target, by aligning to at least one natural fiducial of the annular target and engaging with the portion of the annular target aligned with the at least one natural fiducial; and

FIG. **11** is a schematic illustration of the heart valves including certain examples of natural fiducials.

While the disclosure of the methods implementable using the alignment and engagement systems disclosed herein is amenable to various modifications and alternative forms, specifics thereof have been shown by way of example in the drawings and will be further described in detail below. It should be understood, however, that the intention is not to limit the disclosure to the particular exemplary implementations described. On the contrary, the intention is to cover all modifications, equivalents, and alternatives.

DETAILED DESCRIPTION

Provided herein are exemplary implementations of methods, systems, subsystems and kits for aligning an annuloplasty ring or its first toroidal portion to at least one natural fiducial of an annular target and engage a portion of the annular target aligned with the at least one natural fiducial. The annular target can be, for example: a pulmonary valve, a mitral valve, a tricuspid valve, and an aortic valve.

Furthermore, and as is typically the case, the three dimensional profile of the annulus in some of these valves is dynamic during the cardiac cycle absent implantation of the annuloplasty ring or its toroidal portion, making proper alignment using the methods and systems disclosed beneficial for proper operation of the valves. Furthermore, in the context of the disclosure, the term annuloplasty ring, or its toroidal portion does not necessarily mean a ring defining a single plane, but rather encompasses other planes, for example, a saddle-shaped ring.

Likewise, the term "its (first, second) toroidal portion" means, in the context of the disclosure, any part of the ring operable to be adjoined to form the full annuloplasty ring. For example, in certain implementations, the toroidal portion can be less than half the full ring, or less than a quarter of the full ring and be operable to adjoin other components and form the full annuloplasty ring.

Definitions

The term "coupled," including its various forms such as "operably coupling," "coupling" or "couplable," refers to and comprises any direct or indirect structural coupling, connection or attachment, or adaptation or capability for such a direct or indirect structural or operational coupling, connection or attachment, including integrally formed components and components which are coupled via or through another component or by the forming process. Indirect coupling may involve coupling through an intermediary member or adhesive, or abutting and otherwise resting against, whether frictionally or by separate means without any physical connection.

In addition, for the purposes of the present disclosure, directional or positional terms such as "top," "bottom," "upper," "lower," "side," "front," "frontal," "forward," "rear," "rearward," "back," "trailing," "above," "below," "left," "right," "radial," "vertical," "upward," "downward," "outer," "inner," "exterior," "interior," "intermediate," "apical," "basal," etc., are merely used for convenience in describing the various exemplary implementations of the present disclosure.

Likewise, the term "engage" and various forms thereof, when used with reference to an engaging element, for example in the engagement of washer **302** in docking member **301** between the pair release cords **103**, refers in an exemplary implementation to the application of any forces that tend to hold docking member **301** and a pair of release cords **103** together against inadvertent or undesired separating forces (e.g., such as may be introduced during alignment/engagement and manipulation of the annuloplasty ring or its toroidal portion). It is to be understood, however, that engagement does not in all cases require an interlocking connection that is maintained against every conceivable type or magnitude of separating force. Further, the term "engaging element" refers in another exemplary implementation to one or a plurality of coupled components, at least one of which is configured for releasably engaging another element. Thus, this term encompasses both single part engaging elements and multi-part assemblies, for example, coupling assembly **303** as a whole.

The terms "first," "second," and the like herein do not denote any order, quantity, or importance, but rather are used to denote one element from another. The terms "a," "an" and "the" herein do not denote a limitation of quantity, and are to be construed to cover both the singular and the plural, unless otherwise indicated herein or clearly contradicted by context. The suffix "(s)" as used herein is intended to include both the singular and the plural of the term that it modifies, thereby including one or more of that term (e.g., lance-member(s) **2014*j*** includes one or more lance members).

Reference throughout the specification to "one exemplary implementation," "another exemplary implementation," "an exemplary implementation," and so forth, means that a particular element (e.g., step, feature, structure, and/or characteristic) described in connection with the exemplary implementation is included in at least one exemplary implementation described herein, and may or may not be present in other exemplary implementations. In addition, it is to be understood that the described elements may be combined in any suitable manner in the various exemplary implementations.

In the context of the disclosure, the term "operable" means the system and/or the device, or a certain element or step is fully functional, sized, adapted and calibrated, comprises elements for, and meets applicable operability requirements to perform a recited function when activated, coupled, implemented, actuated, effected, or realized. In relation to systems, the term "operable" means the system is fully functional and calibrated, having the necessary elements, as well as the mechanisms for, and meets applicable operability requirements to perform a recited function when executed by a user.

The term "abut" refers in the context of the disclosure, to items that are in direct physical contact with each other, although the items may not be attached, secured, fused, glued, sewn, or welded together.

In the context of the disclosure, the term "natural fiducial" is used to describe an identifiably distinctive anatomical feature including, without limitation, the right fibrous trigon, left fibrous trigon, interleaflet triangle, tricuspid posterior-anterior hinge, or a combination comprising one or more of the foregoing.

In the context of the disclosure, the term "aligned" is a broad term and is generally meant to include, without limitation, having a fixed angular relationship between about 0 degrees and about 180 degrees between at least one alignment and engagement construction, the delivery catheter, or a marker on the annuloplasty ring or its toroidal portion, and at least one natural fiducial.

In the context of the disclosure, the term "saddle-shaped" is used herein to mean an annuloplasty ring generally made of two arcuate members, for example, two toroidal portions with each toroidal portion having an apex and two ends connecting the toroidal portions. The apex of the toroidal portion in one member can be in the same or opposite direction of the other member. The formed ring can be generally D-shaped.

A more complete understanding of the methods, systems, subsystems and kits for aligning an annuloplasty ring or its first toroidal portion to at least one natural fiducial of an annular target and engaging the portion of the annular target aligned with the at least one natural fiducial can be obtained by reference to the accompanying drawings. These figures (also referred to herein as "FIGS.") are merely schematic representations based on convenience and the ease of demonstrating the present disclosure, and are, therefore, not intended to indicate relative size, scale and dimensions of the devices or components thereof, and/or to define or limit the scope of the exemplary implementations. Although specific terms are used in the following description for the sake of clarity, these terms are intended to refer only to the particular structure of the exemplary implementations selected for illustration in the drawings, and are not intended to define or limit the scope of the disclosure. In the drawings and the following description below, it is to be understood that like numeric designations refer to components of like function.

FIGS. **1-3** illustrate an exemplary implementation of the alignment and engagement device. As illustrated, device **10** is operable to align to at least one natural fiducial (see, e.g., **511**, **512**, FIG. **11**) of an annular target and engage a location of the portion of the annular target aligned with the at least one natural fiducial (see, e.g., **1000**, FIG. **10**A), device **10** comprising: an annuloplasty ring **100** or a first toroidal portion thereof, each having an outer hollow tube **101** with a plurality of slotted backbone **104** (see, e.g., FIG. **3**) therein, annuloplasty ring **100** or its toroidal portion (not shown), with a plurality of segments formed by slotted ribbon **104** (see, e.g., commonly assigned U.S. application Ser. No. 16/702,338, filed Mar. 12, 2019 and titled "STABILIZING AND ADJUSTING TOOL FOR CONTROLLING A MINIMALLY INVASIVE MITRAL/TRICUSPID VALVE REPAIR SYSTEM," which is incorporated herein in its entirety), are each operable to change from an insertion configuration to an operable configuration; alignment and engagement construction comprising at least one cannula **105**, **105'**, each cannula **105**, **105'** having sleeve **106**, **106'** coupled to distal end of cannula **105**, **105'**, each sleeve being releasably coupled to outer hollow tube **101**, or, in other exemplary implementations, to wrapper **102** via coupling sub-assembly **107**, **107'**, the construction operable to align the at least one natural fiducial and engage the location of the portion of the annular target aligned with the at least one natural fiducial; and delivery catheter **108** having proximal end **1080** and distal end **1081**, adapted, sized and configured to accommodate: the alignment and engagement construc-

tion, coupling sub-assembly **107**, **107'** and annuloplasty ring **100** or the first toroidal portion thereof in its insertion configuration, and wherein delivery catheter **108** is operable, once annuloplasty ring **100** or its first toroidal portion is inserted, to alter annuloplasty ring **100** or its first toroidal portion from the insertion configuration to the operable configuration. Also illustrated in FIGS. **1-3** are release cords **103** and anchors **150***i*, forming a portion of the one or more zones such as, for example, a posterior zone (as illustrated by element **150***i* in FIG. **1**, **1501***i* in FIG. **10**F, and **1502***i* in FIG. **10**H), each zone comprising a plurality of internal anchor members **1501***i*, **1502'** located at least partially within outer hollow tube **101**, the zones of the annuloplasty ring, or the second toroidal portion thereof disposed opposite (e.g., **1502'** location) the alignment and engagement construction, each it h anchor **150***i* operable to selectably extend radially from outer hollow tube **101** and engage portion **1000**, **1001** (see, e.g., FIG. **10**A) of the annular target.

FIG. **4** illustrates each cannula **105**, **105'** as comprising harpoon **200** operable to engage the portion of the annular target, at a location aligned with the at least one natural fiducial (see, e.g., **511**, **512**, FIG. **11**, and FIG. **10**D). As illustrated, in an exemplary implementation, harpoon **200** comprises: self-penetrating tip **201**; foreshaft **202** distally coupled to self-penetrating tip **201**; foreshaft **202** defining radial (XR) aperture **2020** disposed along the foreshaft **202** longitudinal axis XL; pushrod **203**, having a proximal end defining axial socket **2030** sized to accommodate a (distal) portion of foreshaft **202**, releasably coupled to the distal end **2021** (see, e.g., FIG. **5**A) of foreshaft **202**; optionally, tether **204** looped through radial aperture **2020**; and optionally, at least one spur **205**, operably coupled to the self-penetrating tip, configured to transition from a first insertion position (see, e.g., FIG. **4**) to a second anchoring position (see, e.g., FIGS. **5**A, **10**D). In certain exemplary embodiments, pushrod **203** is a hollow tube, operable to both accommodate optional tether **204**, or additionally, or alternatively, deliver other structural members, compositions and the like, to the engagement site, as well as remove portions of the engagement site.

In certain exemplary implementations, each sleeve **106**, **106'** used in the devices disclosed for implementing the methods provided, is sized and configured to accommodate self-penetrating tip **201**, foreshaft **202**, and optionally, at least one spur **205**.

Under certain circumstances, and as illustrated in FIGS. **5**B-**7**B, self-penetrating tip **201**, foreshaft **202** and at least one spur **205** are all integrated to single penetrating head **2000**, wherein single penetrating head **2000** is operable to transition between an insertion configuration as illustrated in FIGS. **5**B, **5**C and an anchoring configuration as illustrated in FIGS. **6**A-**7**B. As illustrated in FIGS. **5**B-**7**B, single penetrating head **2000** comprised of a plurality of lancing members (in other words, a multi-lance split tip), configured to have a cross section **2124***p*, **2014***j* operable to form filled cylinder single penetrating head **2000** in the insertion configuration, the filled cylinder having a conical tip **2121***p*, **2011***j* (see, e.g., FIGS. **6**A, **7**A, **7**B). Additionally, or alternatively, in certain exemplary implementations, one or both harpoons **200** can be configured to comprise single penetrating head **2000** (multi-lance split tip) having a plurality of lancing members **2125***p*, configured to form, in the insertion configuration as illustrated in FIG. **6**B, with a cross section **2124***p*, operable to form a hollow cylinder having a frustoconical conical tip **2122***p*. As illustrated in FIGS. **6**A-**8**, upon actuation, each of the lancing members is configured to curve whereby tip **2011***j*, **2121***p*, **2131***q* of each lancing head is directed, in other words pointing to the distal end of a single penetrating head **2000**.

As further illustrated in FIGS. **5**B, **7**B and **8**, showing exemplary implementation of a single penetrating head **2000** comprised of a plurality of lancing members **2010***j* (in other words, a multi-lance split tip), configured to have a cross section **2124***p*, **2014***j* operable to form filled cylinder single penetrating head **2000** in the insertion configuration, the filled cylinder having a conical tip **2121***p*. When curved back, lancing members **2010***j* having a length of between about 0.01 mm and about 5.00 mm, are each configured to form angle a, defined between the tangent of each curved lancing member **2010***j*, and longitudinal axis XL of single penetrating head **2000**.

FIGS. **9**A-**9**C illustrate the components of the alignment and engagement constructions, with FIG. **9**A, illustrating sleeve **106**, **106'**, FIG. **9**B illustrating docking member **301**, and FIG. **9**C illustrating the releasable coupling sub-assembly **107**, **107'** of sleeve **106**, **106'** to docking member **301** in the presence of release cords **103**. Accordingly, and as illustrated in FIG. **9**A, each sleeve **106**, **106'** further comprises dorsal peg **1063** extending radially from each sleeve **106**, **106'**, whereby each sleeve **106**, **106'** having open proximal end **1060**, and open distal end **1062**. Furthermore, each coupling sub-assembly **107**, **107'** comprises docking member **301** coupled to outer hollow tube **101**, or wrapper **102**, operable to releasably engage sleeve **106**, **106'**. As further illustrated in FIG. **9**C, each coupling sub-assembly **107**, **107'** further comprises: washer **302**, operably coupled to peg **1063**, forming a flanged peg; and pair of release cords **103**, wherein docking member **301** having arcuate apical surface **3010** with a diameter configured to abut the curvature of outer hollow tube **101** of annuloplasty ring **100**, or its toroidal portion, docking member **301** further defines opening **3025** having a cylindrical internal surface with diameter D**301** of between about 2.0 mm and about 5.0 mm, configured to accommodate the flanged peg, with two pairs **3022**, **3022'** and **3023**, **3023'** of diametrically aligned openings defined in docking member **301**, the distance (W**301**) between each pair **3022**, **3022'** and **3023**, **3023'** sized and configured to be wider than the (dorsal) peg **1063** and narrower than the flange defined by washer **302** diameter, such that each pair of release cords **103** is threaded through the diametrically opposed openings **3022**, **3022'** and **3023**, **3023'** between the flange and sleeve **106**, **106'** (see, e.g., FIG. **9**C).

In certain exemplary implementations, and as illustrated schematically in FIG. **11**, the at least one natural fiducial is the right fibrous trigon **512**, the left fibrous trigon **511**, the interleaflet triangle (not shown), and the tricuspid posterior-anterior hinge **5031**, and wherein the annular target is at least one of: mitral valve **502**, tricuspid valve **503**, aortic valve **501**, and pulmonary valve **504**. For example, in an exemplary implementation, the annular target is mitral valve (MV) **502**, the natural fiducials are right fibrous trigon **512** and left fibrous trigon **511** and wherein sleeves **106**, **106'** are radially spaced apart to align with right fibrous trigon **512** and left fibrous trigon **511**, sequentially or simultaneously and engage anterior portion **5022** of mitral valve annulus **5020** at the location, or point of contact with anterior portion **5022** that is aligned with right fibrous trigon **512** and left fibrous trigon **511**, see, e.g., FIG. **10**D.

In an exemplary implementation, the methods disclosed herein are implemented using the devices and systems disclosed herein. Accordingly, provided herein is a method for aligning an annuloplasty ring, or its first toroidal portion

to at least one natural fiducial of an annular target and engage a portion of the annular target aligned with the at least one natural fiducial, implementable in a system comprising an annuloplasty ring **100**, or a first toroidal portion thereof, each having an outer hollow tube **101** with a plurality of slotted backbone **104** therein, the annuloplasty ring **100** or its toroidal portion are each operable to change from an insertion configuration to an operable configuration; an alignment and engagement construction comprising at least one cannula **105**, **105**, ' the cannula having a sleeve **106**, **106'** coupled to a distal end **1050** (see, e.g., FIG. **2**) of the cannula **105**, **105'**, the sleeve **106**, **106'** being releasably coupled to the outer hollow tube **101** via a coupling sub-assembly **107**, **107'**, the construction operable to align the at least one natural fiducial (see, e.g., **511**, **512**, FIG. **11**) and engage a portion of the annular target aligned with the at least one natural fiducial; and a delivery catheter **108** having a proximal end **1080** and a distal end **1081**, adapted, sized and configured to accommodate: the alignment and engagement construction, the coupling sub-assembly **107**, **107'** and the annuloplasty ring **100** or the first toroidal portion thereof in its insertion configuration, and wherein the delivery catheter **108** is operable, once the annuloplasty ring **100** or its first toroidal portion is inserted, to alter the annuloplasty ring **100** or its first toroidal portion from the insertion configuration to the operable configuration, the method comprising: using the delivery catheter **108**, introducing the annuloplasty ring **100** or the first toroidal portion thereof to the annular target site (see, e.g., **601**, FIG. **10**A); using the delivery catheter, altering the insertion configuration of the annuloplasty ring **100** or the first toroidal portion thereof to the operable configuration; using the alignment and engagement construction, aligning (see, e.g., **602**, FIG. **10**B) the at least one sleeve **106**, **106'** with the at least one natural fiducial (see, e.g., **511**, **512**, FIG. **11**); engaging the annular target (see, e.g., **603**, FIG. **10**C) at the location aligned with the at least one natural fiducial (see, e.g., **511**, **512**, FIG. **11**); and releasing the sleeve **106**, **106'** from the outer hollow tube **101**. Furthermore, the step of engaging the annular target at the location aligned with the at least one natural fiducial comprises: using the pushrod **203**, penetrating the location aligned with the at least one natural fiducial with the self-penetrating tip **201**, wherein at least a portion of the foreshaft **202** remains external to the location aligned with the at least one natural fiducial; and optionally transitioning the at least one spur **205** to the anchoring position (see, e.g., FIGS. **5**A, **10**D). Likewise, the step of releasing the sleeve **106**, **106'** from the outer hollow tube **101** comprises: pulling the release cords **103**; and using the delivery catheter **108**, releasing the sleeve **106**, **106'** from the outer hollow tube (see, e.g., **610-612**, FIGS. **10**J-**10**L). In certain exemplary implementations, the method for aligning an annuloplasty ring or its first toroidal portion to at least one natural fiducial of an annular target and engage a portion of the annular target aligned with the at least one natural fiducial further comprises comprising: either simultaneously or sequentially, with releasing the pushrod from the foreshaft, using the delivery catheter **108**, maneuvering (**605**, FIG. **10**E) the one or more zones **1051***i*, each comprising the plurality of internal anchor heads **150***i* of the annuloplasty ring **100** or the second toroidal portion thereof to the posterior rim **5021** (see, e.g., FIG. **11**) of the mitral valve **502**; deploying (**606**, FIG. **10**F) the anchors **1052***i* thereby engaging the posterior rim **5021** of the mitral valve **502**; using tethers **204**, pulling (**607**, FIG. **10**G) the posterior rim **5021** of the mitral valve **502** toward the anterior rim **5022**, aligned with natural fiducials **512**, **511**. Thereafter, deploying (**608**, FIG. **10**H) the anchors **1052***i* configured to engage the anterior rim **5022** of the mitral valve **502**; anchoring the anterior rim **5022** of the mitral valve **502** to the annuloplasty ring **100** or the first toroidal portion thereof; pulling (**610**, FIG. **10**J) the release cords **103**, thereby releasing the sleeve **106**, **106'** from the annuloplasty ring **100** or the first toroidal portion thereof; using the delivery catheter **108**, retracting (**611**, FIG. **10**K) each cannula **105**, **105'** and sleeve **106**, **106'**; and releasing (**612**, FIG. **10**L) the annuloplasty ring **100** or the first toroidal portion thereof from the delivery catheter **108**.

While in the foregoing specification the methods, systems, subsystems and kits for aligning an annuloplasty ring or a toroidal portion thereof with at least one natural fiducial in an annular target and engage a portion of the annular target at a location aligned with the at least one natural fiducials described herein have been described in relation to certain exemplary implementations, and many details are set forth for purposes of illustration, it will be apparent to those skilled in the art that the disclosure of the alignment methods, implementable using the systems disclosed herein, are susceptible to additional implementations and that certain of the details described in this specification and as are more fully delineated in the following claims can be varied considerably without departing from the basic principles disclosed herein.

What is claimed:

1. A device operable to align to at least one natural fiducial of an annular target and engage a portion of the annular target aligned with the at least one natural fiducial, the device comprising:

an annuloplasty ring, or a first toroidal portion thereof, each having an outer hollow tube comprising a backbone with a plurality of slots therein, the annuloplasty ring or a toroidal portion thereof are each operable to change from an insertion configuration to an operable configuration;

an alignment and engagement construction comprising at least one cannula, each cannula of the at least one cannula having a sleeve coupled to a distal end of the cannula, the sleeve being releasably coupled to the outer hollow tube via a coupling sub-assembly, the construction operable to align with the at least one natural fiducial and engage a portion of the annular target aligned with the at least one natural fiducial; and

a delivery catheter having a proximal end and a distal end, adapted, sized and configured to accommodate: the alignment and engagement construction, the coupling sub-assembly and the annuloplasty ring or the first toroidal portion thereof in the insertion configuration, and wherein the delivery catheter is operable, once the annuloplasty ring or the first toroidal portion is inserted, to alter the annuloplasty ring or the first toroidal portion from the insertion configuration to the operable configuration.

2. The device of claim **1**, wherein each cannula of the at least one cannula comprises a harpoon operable to engage a portion of the annular target aligned with the at least one natural fiducial.

3. The device of claim **2**, wherein the harpoon comprises:

a self-penetrating tip;

a foreshaft distally coupled to the self-penetrating tip, the foreshaft defining a radial aperture disposed along a longitudinal axis of the foreshaft;

a pushrod, having a proximal end defining an axial socket sized to accommodate a portion of the foreshaft, releasably coupled to a distal end of the foreshaft;

optionally, a tether looped through the radial aperture; and

optionally, at least one spur, operably coupled to the self-penetrating tip, configured to transition from a first insertion position to a second anchoring position.

4. The device of claim **3**, wherein each sleeve is sized and configured to accommodate the self-penetrating tip, the foreshaft, and optionally, the at least one spur.

5. The device of claim **4**, wherein each sleeve further comprises a dorsal peg extending radially from the sleeve.

6. The device of claim **5**, wherein each coupling sub-assembly comprises a docking member coupled to the outer hollow tube, operable to releasably engage the sleeve.

7. The device of claim **6**, wherein each coupling sub-assembly further comprises:

a washer, operably coupled to the peg, forming a peg with a flange; and

a pair of release cords, wherein the docking member further defines an opening having a cylindrical internal surface, configured to accommodate the peg, with two pairs of diametrically aligned openings defined in the docking member, a distance between each pair sized and configured to be wider than the peg and narrower than the flange, such that the pair of release cords is each threaded through the diametrically opposed openings between the flange and the sleeve.

8. The device of claim **7**, wherein the pair of release cords are operably coupled to the proximal end of the delivery catheter.

9. The device of claim **1**, wherein the at least one natural fiducial is at least one of a right fibrous trigon, a left fibrous trigon, an interleaflet triangle, and a tricuspid posterior-anterior hinge.

10. The device of claim **9**, wherein the annular target is at least one of: a mitral valve, a tricuspid valve, an aortic valve, and a pulmonary valve.

11. The device of claim **10**, wherein the annular target is the mitral valve, the natural fiducials are the right fibrous trigon and the left fibrous trigon and wherein the sleeves are radially spaced to align with the right fibrous trigon and the left fibrous trigon, sequentially or simultaneously and engage an anterior portion of a mitral valve annulus at the location aligned with the right fibrous trigon and the left fibrous trigon.

12. The device of claim **3**, wherein the self-penetrating tip, the foreshaft and the at least one spur are integrated into a single penetrating head.

13. The device of claim **12**, wherein the single penetrating head is operable to transition between an insertion configuration and an anchoring configuration.

14. The device of claim **13**, wherein the single penetrating head is comprised of a plurality of lancing members, configured to form a filled cylinder having a conical tip.

15. The device of claim **13**, wherein the single penetrating head is comprised of a plurality of lancing members, configured to form a hollow cylinder having a frusto-conical conical tip.

16. The device of claim **14**, wherein upon actuation, each lancing member of the plurality of lancing members is configured to curve whereby the tip of each lancing member is directed to a distal end of the single penetrating head.

17. A method for aligning an annuloplasty ring or a first toroidal portion thereof to at least one natural fiducial of an annular target and engage a portion of the annular target aligned with the at least one natural fiducial, implementable in a system comprising an annuloplasty ring, or a first toroidal portion thereof, each having an outer hollow tube comprising a backbone with a plurality of slots therein, the annuloplasty ring or the toroidal portion are each operable to change from an insertion configuration to an operable configuration; an alignment and engagement construction comprising at least one cannula, each cannula of the at least one cannula having a sleeve coupled to a distal end of the cannula, the sleeve being releasably coupled to the outer hollow tube via a coupling subassembly, the construction operable to align with the at least one natural fiducial and engage a portion of the annular target aligned with the at least one natural fiducial; and a delivery catheter having a proximal end and a distal end, adapted, sized and configured to accommodate: the alignment and engagement construction, the coupling sub-assembly and the annuloplasty ring or the first toroidal portion thereof in the insertion configuration, and wherein the delivery catheter is operable, once the annuloplasty ring or the first toroidal portion is inserted, to alter the annuloplasty ring or the first toroidal portion from the insertion configuration to the operable configuration, the method comprising:

using the delivery catheter, introducing the annuloplasty ring or the first toroidal portion thereof to an annular target site;

using the delivery catheter, altering the insertion configuration of the annuloplasty ring or the first toroidal portion thereof to the operable configuration;

using the alignment and engagement construction, aligning the at least one sleeve with the at least one natural fiducial;

engaging the annular target at the location aligned with the at least one natural fiducial; and

releasing the sleeve from the outer hollow tube.

18. The method of claim **17**, wherein each cannula of the at least one cannula comprises a harpoon operable to engage the natural fiducial.

19. The method of claim **18**, wherein the harpoon comprises:

a self-penetrating tip;

a foreshaft distally coupled to the self-penetrating tip, the foreshaft defining a radial aperture disposed along a longitudinal axis of the foreshaft;

a pushrod, having a proximal end defining an axial socket sized for and releasably coupled to a distal end of the foreshaft;

optionally, a tether looped through the radial aperture; and

optionally, at least one spur, operably coupled to the self-penetrating head, configured to transition from a first insertion position to a second anchoring position.

20. The method of claim **19**, wherein the step of engaging the annular target at the location aligned with the at least one natural fiducial comprises:

using the pushrod, penetrating the location aligned with the at least one natural fiducial with the self-penetrating tip, wherein at least a portion of the foreshaft remains external to the location aligned with the at least one natural fiducial; and

optionally, transitioning the at least one spur to the anchoring position.

21. The method of claim **20**, wherein each sleeve is sized and configured to accommodate the self-penetrating tip, the foreshaft, and optionally, the at least one spur.

22. The method of claim **21**, wherein each sleeve further comprises a dorsal peg extending radially from the sleeve.

23. The method of claim **22**, wherein each coupling sub-assembly comprises a docking head coupled to the outer hollow tube, operable to releasably engage the sleeve.

24. The method of claim **23**, wherein each coupling sub-assembly further comprises:

a washer, operably coupled to the peg, forming a peg with a flange; and

a pair of release cords, wherein the docking head further defines an opening having a cylindrical internal surface, configured to accommodate the peg, with two pairs of diametrically aligned openings defined in the docking head, a distance between each pair sized and configured to be wider than the peg and narrower than the flange, such that the pair of release cords is each threaded through the diametrically opposed openings between the flange and the sleeve.

25. The method of claim **24**, wherein the step of releasing the sleeve from the outer hollow tube comprises:

pulling the release cords; and

using the delivery catheter, releasing each sleeve from the outer hollow tube.

26. The method of claim **20**, wherein the annuloplasty ring or a second toroidal portion thereof has one or more zones, each zone comprising a plurality of internal anchor heads located at least partially within the outer hollow tube, the zones of the annuloplasty ring, or the second toroidal portion thereof disposed opposite the alignment and engagement construction, each internal anchor head of the plurality of internal anchor heads are operable to selectably extend radially from the outer hollow tube and engage a portion of the annular target.

27. The method of claim **26**, wherein the at least one natural fiducial is at least one of a right fibrous trigon, a left fibrous trigon, an interleaflet triangle, and a tricuspid posterior-anterior hinge.

28. The method of claim **27**, wherein the annular target is at least one of: a mitral valve, a tricuspid valve, an aortic valve, and a pulmonary valve.

29. The method of claim **28**, wherein the annular target is the mitral valve, the natural fiducials are the right fibrous trigon and the left fibrous trigon, and wherein the sleeves are radially spaced to align with and engage the right fibrous trigon and the left fibrous trigon, sequentially or simultaneously.

30. The method of claim **29** further comprising:

either simultaneously or sequentially, with releasing the pushrod from the foreshaft;

using the delivery catheter, maneuvering the one or more zones, each comprising the plurality of internal anchor heads of the annuloplasty ring or the second toroidal portion thereof to a posterior rim of the mitral valve;

deploying the plurality of internal anchor heads of the second toroidal portion thereby engaging the posterior rim of the mitral valve; and

using the tethers, pulling the posterior rim of the mitral valve toward the natural fiducials.

31. The method of claim **30**, wherein the annuloplasty ring or the first toroidal portion thereof has one or more zones, each zone comprising a plurality of internal anchor heads located at least partially within the outer hollow tube, the zones of the annuloplasty ring, or the first toroidal portion thereof, each internal anchor head of the plurality of internal anchor heads are operable to selectably extend radially from the outer hollow tube in line with the alignment and engagement construction, and engage an anterior portion of the mitral valve.

32. The method of claim **31**, further comprising:

deploying the plurality of internal anchor heads of the first toroidal portion configured to engage an anterior rim of the mitral valve;

anchoring the anterior rim of the mitral valve to the annuloplasty ring or the first toroidal portion thereof;

pulling release cords, thereby releasing the sleeve from the annuloplasty ring or the first toroidal portion thereof;

using the delivery catheter, retracting each cannula and sleeve; and

releasing the annuloplasty ring or the first toroidal portion thereof from the delivery catheter.

33. The method of claim **32**, wherein the first toroidal portion and the second toroidal portion are operable to form the annuloplasty ring.

34. The method of claim **19**, wherein the self-penetrating tip, the foreshaft and optionally the at least one spur are integrated to a single penetrating head.

35. The method of claim **34**, wherein the single penetrating head is operable to transition between an insertion configuration and an anchoring configuration.

36. The method of claim **35**, wherein the single penetrating head is comprised of a plurality of lancing members, configured to form a filled cylinder having a conical tip.

37. The method of claim **35**, wherein the single penetrating head is comprised of a plurality of lancing members, configured to form a hollow cylinder having a frusto-conical conical tip.

38. The method of claim **36**, further comprising:

actuating the single penetrating head; and

curving the tip of each lancing member of the plurality of lancing members to direct the tip to a distal end of the single penetrating head.

* * * * *